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# Asian Biotechnology and Development Review

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## **Special Issue on Biosafety and Socio-economic Considerations**

**Socio-economic Considerations under the Cartagena Protocol  
on Biosafety: Insights for Effective Implementation**  
*Georgina Catacora-Vargas*

**Socio-economic Aspects in Decision-Making in the Context of the  
Biosafety Protocol: Malaysia's Experience and Case Studies**  
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**Multiple Meanings, One Objective: The Case of Biotechnology  
Policy Convergence in Africa**  
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**Socioeconomics, Biosafety, and Sustainable Development**  
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**Governance of Biotechnology in Africa: The Challenge of  
Reconciling Interdependencies and Differences**  
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**Socio-economic Considerations and LMOs:  
The Case for an Appropriate and Integrated Framework**  
*Sachin Chaturvedi, Krishna Ravi Srinivas and Pallavi Singh*



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# Socio-economic Considerations under the Cartagena Protocol on Biosafety: Insights for Effective Implementation

Georgina Catacora-Vargas\*

**Abstract:** The inclusion of the socio-economic aspects in environmental decision-making has been practiced since the early seventies. The interactions between the environment and society, the growing demand for social responsibility and the pledge towards sustainable development are some of its drivers. However, in multilateral environmental agreements, particularly in the Cartagena Protocol on Biosafety (CPB), the integration of socio-economic matters in decision-making has been difficult and contentious. Article 26 of the CPB relates to socio-economic considerations arising from the impact of living modified organisms (LMOs) on the conservation and sustainable use of biological diversity. Contrary to the opinion of some scholars and the biotechnology industry, this article argues that Article 26 of the CPB: (a) recognises the sovereign rights of States in taking into account socio-economic considerations when making a decision of import of LMOs; (b) it has a wide scope since it deals with broad issues, namely conservation and sustainable use of biodiversity; and (c) is a cross-cutting article within the CPB since, when included in decision-making, it relates to several operational provisions. Accordingly, the implementation of the CPB would be incomplete and not consistent with its objectives if socio-economic considerations are not appropriately and timely addressed in biosafety decision-making processes.

**Key words:** Living modified organisms, socio-economic considerations, Cartagena Protocol on Biosafety, decision-making.

## Briefing on the Current Status of Socio-economic Considerations under the Cartagena Protocol on Biosafety

The interconnections among ecological, social and economic aspects of any intervention (e.g. projects and technologies) have already received broad

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acknowledgement in the international environmental community, and thus have a substantial trajectory on environmental decision-making. Practical applications of the eco-social interrelation started in the early 1970s when legislations begun to incorporate social impact assessments in their environmental procedures (Freudenburg 1986). Since then, the inclusion of socio-economic considerations in environmental decision-making processes has increased as a result of: (i) the evident mutual influence between the environment and society; (ii) growing demand for social responsibility by markets and regulations; and (iii) the imperative in advancing agendas towards sustainable development (Barrow 2002).

Despite this progress – especially on the integration of the environmental and socio-economic fields at regulatory and research levels for assessing the drivers, impacts and outcomes of technology use – the incorporation of socio-economic considerations in multilateral environmental agreements (MEA) has been rather contentious. This is particularly true for the issue of the safety assessment of genetically modified organisms (GMOs) under the Cartagena Protocol on Biosafety (CPB), due to the politically charged and large economic incentives at stake.

The CPB is a MEA that aims at contributing to the safe transfer, handling and use of GMOs (referred in the Protocol as living modified organisms or LMOs) resulting from modern biotechnology. The focus of the Protocol is to prevent “*adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health*” (Article 1) (Secretariat of the CBD 2000:3).

The negotiations of the text of the CPB took from 1995 to 2000 (year of its adoption). During this time, the inclusion of socio-economic aspects related to LMOs was one of the most difficult and contentious discussions, due to two opposing positions. On one hand, developing countries had wanted to include socio-economic considerations in risk assessment, risk management and decision-making procedures on LMOs. Several arguments on anticipated changes and potential threats were presented in this respect, particularly with regard to centers of origin and genetic diversity (e.g. impacts on biological diversity that may jeopardise rural livelihoods, indigenous knowledge, market opportunities and even national economies, among others) (MacKenzie *et al.* 2003; Khwaja 2002). On the other hand, most developed countries argued that socio-economic considerations were subjects “of little relevance and believed that further studies on the matter were not necessary” (Secretariat of the CBD 2003:79). Accordingly, they

sustained that social and economic issues were of reduced relevance in the context of the CPB since, in their view, they mostly relate to national interests (MacKenzie *et al.* 2003). The result of this long-standing debate is a broad compromise text on socio-economic considerations in Article 26 of the CPB. After the Protocol's entry into force, the process of decision-making involving concrete measures for implementation of this article has also been characterised by intense discussions and contentious positions among Parties. The outcome to date has thus been a slow process to achieve further clarity and agreed guidance on how to address socio-economic considerations in the context of the CPB.

One standing topic under discussion has been the actual scope and extent of application of socio-economic considerations under the Protocol. Some countries (e.g. Argentina and the United States, both non-Parties to the CPB), some scholars and also the biotechnology industry argue that social and economic aspects should be of narrow scope and voluntary, so that their inclusion in biosafety decision-making do not delay the process of adoption of new technologies or increase the cost of compliance with the Protocol (Falk-Zepeda and Zambrano 2011; Falk-Zepeda 2009, see also the Global Industry Coalition submission in Secretariat of the CBD 2011a). Conversely, other countries (e.g. several from the African Group, Bolivia and Norway), scholars and some international NGOs sustain that Article 26 spells out the right of countries to include socio-economic considerations in the biosafety decision-making process. This position is based on the argument that development and adoption of technologies have a wide array of ecological and socio-economic implications. Moreover, these biosafety actors sustain the importance of effectively addressing the social and economic dimensions of LMO introduction in light of sustainable development (Secretariat of the CBD 2011a; Pavone 2011; MacKenzie *et al.* 2003).

In spite of the unresolved issues and the lack of guidelines for effective implementation of Article 26, socio-economic considerations are integrated in biosafety decision-making and regulatory frameworks in a number of countries. For instance, by 2010, according to Spök (2010), the following sixteen Parties to the CPB incorporate provisions on socio-economic impacts in their national biosafety regulations: Armenia, Austria, Bangladesh, Bhutan, Cambodia, China, France, Honduras, India, Lebanon, Mauritius, Nigeria, Norway, the Philippines, South Korea and Syria.

Contrary to some opinions for restricted application and marginal relevance, the actual language of Article 26 is rather wide in scope and

cross-cutting in nature. This because it deals with the core issues between the CPB and its mother treaty (the Convention on Biological Diversity, CBD): Conservation and sustainable use of biological diversity. Hence, when implemented, Article 26 inherently relates to several other provisions of the Protocol.

The interconnection of Article 26 with several other articles of the CPB is pointed out in the Explanatory Guide to the Cartagena Protocol on Biosafety. This Guide is an internationally recognised document that provides orientation for the interpretation of the CPB, which was prepared by scholars in law and reviewed in a series of workshops by different biosafety stakeholders (including governmental delegates and members of the Intergovernmental Committee for the Cartagena Protocol) (MacKenzie *et al.* 2003). Nonetheless, the relationship of Article 26 with other stipulations of the CPB has not yet been further analysed. The purpose of this article is to provide insights on the wide scope of the Article 26 on socio-economic considerations (specifically on Article 26.1) and its connection to other operational articles of the Protocol.

### **Article 26 of the Cartagena Protocol on Socio-economic Considerations**

Article 26 of the CPB contains two provisions, from which Article 26.1 is operational in relation to biosafety decision-making. Article 26.1 states: *"The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."* (Secretariat of the CBD 2000:19).

The text of Article 26.1 contains a number of relevant elements for analysis. For this article, however, we will focus on only a few: (i) the meaning of the text *"may take into account"* as recognition of the sovereign right of Parties; (ii) the broad scope set by the wording *"conservation and sustainable use of biological diversity"*; and (iii) the cross-cutting nature of Article 26.1 set by the text: *"The Parties, in reaching a decision on import under this Protocol"*.

#### ***"...may take into account" as a Recognition of Sovereign Rights***

The wording *"may take into account"* in Article 26.1 has been interpreted by some as a text that points to a voluntary measure, over stressing that Article 26.1 is not an obligatory CPB provision (GIC 2012;

Falk-Zepeda and Zambrano 2011; Falk-Zepeda 2009). This interpretation has important shortcomings. First, it ignores the context from which the language of Article 26.1 results. In international negotiations, a common practice is the inclusion of compromise texts on contentious matters in order to reflect the various concerns of the different positions. Article 26.1 is a compromise text that, to some extent, addresses the positions of both developing and developed countries during the discussions on the inclusion of socio-economic aspects in the LMOs biosafety process (Khwaja 2002). Second, it erroneously suggests, in a subtle manner, that Article 26.1 would be a provision low in hierarchy of implementation.

Conversely, a more comprehensive analysis is that Article 26.1 establishes the right of Parties to the CPB to take into account socio-economic issues in the decision-making process related to LMOs. As stated by Khwaja (2002:361) – a negotiator of the text of the CPB – “*Article 26 is to empower Parties of import to analyse carefully what possible adverse impacts the import of LMOs would have on their socio-economic conditions*”. Accordingly, its incorporation in biosafety decision-making does not breach the Protocol. This understanding seems consistent with Article 2.4 of the CPB on General Provisions. Article 2.4 acknowledges that the Protocol does not restrict to Parties in taking any measure that may contribute to better protection of the conservation and use of the biological diversity. The literal wording of Article 2.4 is: “*Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party’s other obligations under international law.*” (Secretariat of the CBD 2000:3).

Accordingly, Article 26.1 of the Protocol goes beyond merely stating a voluntary measure but establishes and confirms the right, in international law, of the Parties to take account of socio-economic considerations in biosafety decision-making processes. Whether or not Parties choose to exercise this right is up to them in accordance to their specific social and economic priorities and interests. However, the right is clearly defined, and its recognition as such is particularly relevant for: (a) countries that are centers of origin and genetic diversity, due to the close interconnection between biodiversity and local communities (Serratos 2009; IAASTD ed. 2009); (b) countries that have large indigenous or rural populations given their relationship with and dependence on biodiversity (Maffi and Woodley 2010; CEC 2004); and (c) countries that have an important portion of their

economy and development programmes reliant on the use of biodiversity (e.g. sustainable management of agrobiodiversity as part of local agricultural and development agendas) (IAASTD ed. 2009; Nuffield Council of Ethics 2004).

***Biodiversity Conservation and Sustainable Use: Broad in Themselves***

In the CPB discussions on socio-economic considerations, the position of some countries, observers and stakeholders is that the implementation scope of Article 26.1 is narrow and strictly limited to biodiversity issues (GIC 2012; Secretariat of the CDB 2011a; Falk-Zepeda and Zambrano 2011; Falk-Zepeda 2009). Based on the text of Article 26.1, socio-economic considerations as stated in the Protocol are certainly related to the effects on biological diversity specifically to its conservation and sustainable use, and particularly to the value of biodiversity to indigenous and local communities. Yet, these specifications are far from being narrow when analysed from a technical and, consequently, decision-making point of view.

The specifications in Article 26.1 in relation to biodiversity set its wide scope of application based on the following:

- Biodiversity is a broad concept in itself that embraces all forms of life and their environments (including their living and non-living components). This is described in the CBD's definition on biological diversity and ecosystems as follows: "*Biodiversity*" refers to "*the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part: this includes diversity within species, between species and of ecosystems*"; while "*ecosystem*" is described as: "*dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit*" (Secretariat of the CBD 1992:3).
- Impacts on biodiversity relate to a large spectrum of possible effects. There is widespread and well-documented recognition that any impact on biodiversity or ecosystems does not take place in a linear or necessarily scale-dependent manner. On the contrary, changes in biodiversity are complex and unpredictable, which may result in cumulative and combinatorial effects that can accelerate changes or lead to unintended adverse effects (Cardinale *et al.* 2012). In simpler words, any change on biodiversity can result in a chain of other alterations and consequences either direct, indirect, intentional, accidental, predicted and/or unforeseen (Stabinsky 2001). The wording in Article 26.1

*“socio-economic considerations arising from the impacts of living modified organisms on the conservations and sustainable use of biological diversity”* refers to all these different kinds of possible effects.

- Conservation and particularly sustainable use of biodiversity have an intrinsic socio-economic component. On one hand, the “use” of biodiversity is defined by social, cultural and economic factors. Moreover, the biological and socio-cultural components of life that define the consuetudinary practice (such as use of local biodiversity for food or income generation) are inseparable, particularly among indigenous communities (Prilgrim and Pretty 2010; Maffi 2010; Cardinale *et al.* 2012). On the other hand, the use of biological diversity in a “sustainable manner”, as pledged by the CBD and CPB, entails the management of biodiversity by individuals and groups. Accordingly, the societies and socio-economic factors in which these individuals and groups are embedded play a crucial role in the long-term preservation of biodiversity while securing the fulfilment of the needs of the present and future generations (Borrini-Feyerabend *et al.* 2004).

In summary, the specification of socio-economic considerations “*arising from the impacts of LMOs in relation to the conservation and sustainable use of biodiversity*” is broad in its very essence. It includes the direct, indirect, intentional, accidental, predicted and unforeseen effects on the different forms of life and their environments, and on their potential use in light of the sustainability principles. Furthermore, the text “*especially with regard to the value of biological diversity to indigenous and local communities*” of Article 26.1 keeps its scope appropriately wide by pointing out that besides the broad array of implications on biodiversity and sustainable use in general, additional (and not restricted to) considerations are needed relative to the livelihood, consuetudinary use, culture, spirituality and others where biodiversity plays an important role for indigenous and local communities.

### ***The Cross-Cutting Nature of Article 26 on Socio-economic Considerations***

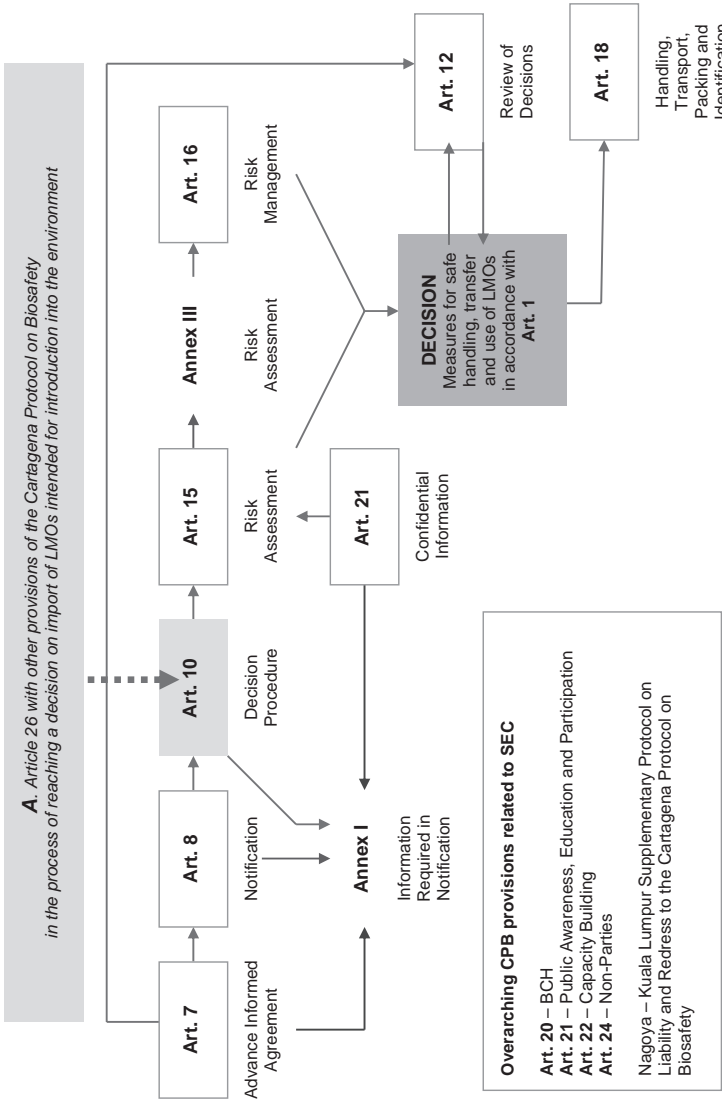
Other proposed interpretations of Article 26 in general, and Article 26.1 in particular, are: (a) It deals with a very specific issue within the Protocol; and (b) If it is to be included in biosafety decision-making, it should be treated in a separate manner in relation to the other provisions, particularly to the risk assessment (Falk-Zepeda and Zambrano 2011). These interpretations mistakenly place Article 26 as an isolated or virtual stand-alone clause. Nonetheless, the text “*The Parties, in reaching a decision on import under this Protocol*” opens up for the inclusion of Article 26 with

respect to other Protocol's provisions when, upon the discretion of Parties, a comprehensive analysis is applied (MacKenzie *et al.* 2003). In this regard, the next paragraphs describe the possible – and non-exhaustive – range of the implications and integration of Article 26 along the whole body of the Protocol.

To begin with, Article 26.1 clearly states that “*in reaching a decision on import*” under the Protocol, Parties may take into account socio-economic considerations. This wording has two important implications. First, it indicates “*when*” socio-economic aspects can be considered: This is at the time of reaching a decision on import. Second, it leads to two key articles related to the general *modus operandi* for taking a decision on import of LMOs: (a) Article 10 on Decision Procedure; and (b) Article 11 on Procedure for Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing. These articles are central in guiding the steps for decision-making under the Protocol and are linked to other important operative provisions (Figure 1, Figure 2 and Figure 3). In light of this, the relationships of Article 26.1 with other Protocol articles would be as follows:

- In relation to Article 10 (see the process A, Figure 1), on one hand, it would arguably relate socio-economic considerations to Article 15 on Risk Assessment and Annex III of the CPB, for taking into account social and economic issues in parallel to the environmental risk assessment. Although Annex III mostly refers to highly technical environmental aspects, the implementation of Article 15 shall also take into account human health (in consistency with the Protocol's objective). This defines the possibility of including in the risk assessment relevant public health issues – a highly relevant socio-economic subject – in relation to adverse effects of LMOs on the conservation and sustainable use of biological diversity. Furthermore, Article 10.3(c) opens up the possibility for including socio-economic considerations in risk assessment processes under the CPB by stating that Parties, in the course of taking a decision, can request “*additional information in accordance with its domestic regulatory framework or Annex I*” (Secretariat of the CBD 2000:7). Accordingly, supplementary information could be, among other things, a socio-economic impact assessment. This approach will lead to a more systemic evaluation of risks and contribute to overcome, at least partly, the current limitations of assessments mostly focused on restricted environmental aspects (Meyer 2011). Additionally, Annex I under item (I) requests information on “*Suggested methods for safe handling, storage, transport and use, including packaging, labeling, [...]*”

**Figure 1: Relationship of Article 26 on socio-economic considerations with other provisions of the Cartagena Protocol on Biosafety in the process of reaching a decision on import of LMOs intended for introduction into the environment**



Source: Author's work.



(Secretariat of the CBD 2000:27). This provision relates to socio-economic matters as well, which are important to identify. For instance, conditions for segregation during storage and transport, or intended and other potential local uses of the LMO in question, are socio-economic considerations that will impact the safe handling, storage, transport and use of LMOs.

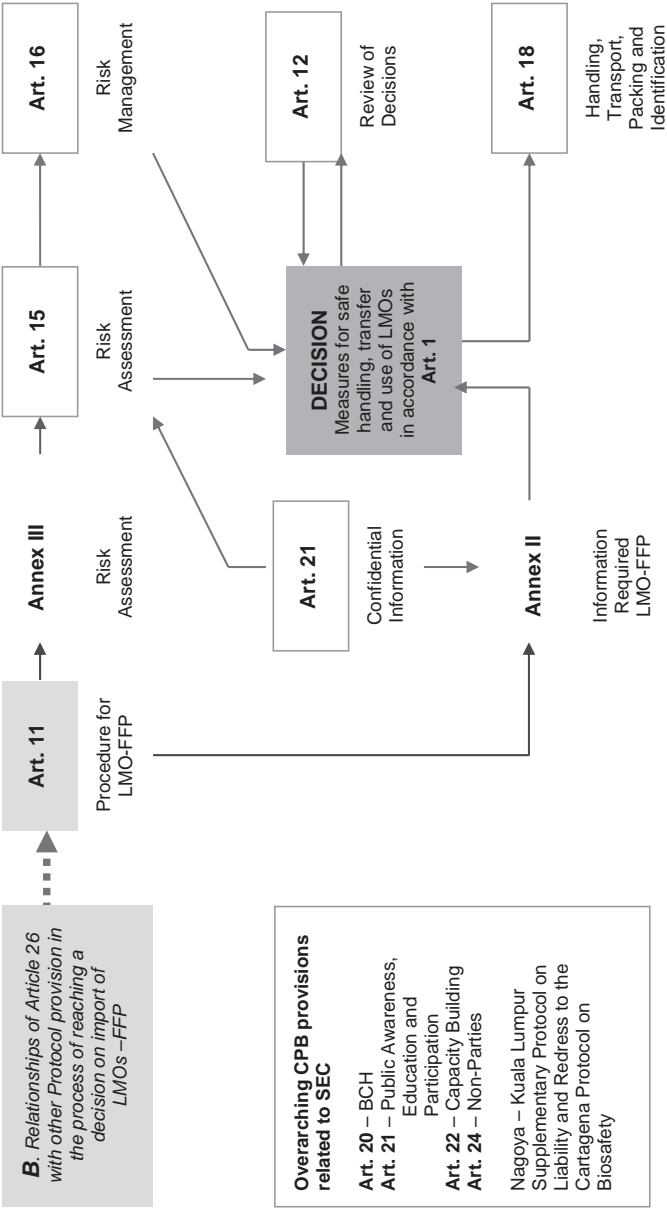
Upstream in the process of decision-making, Article 10, and subsequently Article 26.1, relates to:

- ▶ Article 7 on the Application of the Advance Informed Agreement Procedure (AIA): and
- ▶ Article 8 on Notification, which also refers to Annex I, where – as indicated previously – socio-economic information could be requested by the notified Party.

Downstream, Article 10, and then Article 26.1, is linked to:

- ▶ Article 16 on Risk Management under which measures to prevent or regulate, manage and control socio-economic risks could be identified.
  - ▶ Article 21 on Confidential Business Information that mentions, among others, that information relevant to the risk assessment and the one generated according to Annex I of the CPB cannot qualify as confidential. In relation to risk assessment, “relevant information” could entail information with socio-economic connotations (e.g. in relation to the Protocol’s objectives, findings on impacts on human health from the public health point of view).
  - ▶ Article 12 on Review of Decisions, which indicates that decisions on LMOs could be reviewed in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking into account human health. New scientific information could refer to impacts of LMOs that may have socio-economic implications, including potential changes in human health from the public health perspective.
- In relation to Article 11 (see the process B, Figure 2), is the other provision that would relate to Article 26.1 in the process of taking a decision on import of a LMO, in this case when the LMO is intended for direct use as food or feed, or processing (LMO-FFP). Accordingly, it could be interpreted as allowing the inclusion of socio-economic considerations through:

**Figure 2: Relationship of Article 26 on socio-economic considerations with other provisions of the Cartagena Protocol on Biosafety in the process of reaching a decision on import of LMO-FFP**



Source: Author's work.

- ▶ Annex II specifically under item (k) that requests suggested methods for safe handling, storage, transport and use of LMO-FFPs, since these processes involve socio-economic aspects as described before;
- ▶ Article 15 and Annex III according to Article 11.6(a) on the risk assessment as a source of information for the process of decision-making; and
- ▶ Article 16 on Risk Management and Article 12 on Review of Decisions, in line with what was mentioned previously.

Furthermore, an overarching feature of Article 11 is that it is subject of socio-economic considerations. This is because its implementation is triggered when a Party has adopted a decision “*regarding domestic use, including placing on the market*” of a LMO-FFP (Article 11.1). “*Domestic use*” and “*placing on the market*” are inherently socio-economic processes. Hence, reaching a decision on these matters necessarily social and economic factors need to be taken into account.

Besides Article 10 and Article 11 on the decision procedures on import of LMOs, the implementation of Article 26.1 could also relate to Article 17 and Article 25 as follows (see the process C, Figure 3):

- In relation to Article 17 on Unintentional Transboundary Movements and Emergency Measures, socio-economic issues can be considered for determining the impacts that may arise from such movements and the corresponding response measures. On one side, Articles 17.3(c) and 17.3(d) request available information on possible adverse effects and other relevant information, respectively, in notifications to States affected or potentially affected by unintentional transboundary movements of LMOs. Such information could include socio-economic considerations. On the other side, under Article 17.4 social and economic issues could be taken into account to determine the appropriate responses, necessary actions or emergency measures. Moreover, those response and emergency measures could address the socio-economic impacts arising from adverse effects on the conservation and sustainable use of biodiversity, taking into account human health, and related to unintentional transboundary movement of an LMO. Finally, Article 17 also relates to Article 16 on risk management giving place, as indicated earlier, to the identification of actions to prevent, regulate, manage and control potential risks, which could arguably include socio-economic impacts. Specifically, Parties may incorporate socio-economic considerations in their responses to prevent



unintentional transboundary movements under Article 16.3, and could take appropriate risk management measures to prevent any adverse effect, including socio-economic effects, according to Article 16.2.

- As for Article 25 on Illegal Transboundary Movements, socio-economic considerations may contribute to the identification of any potential adverse effects and the related response measures.

Finally, Article 26 is linked the following overarching CPB articles:

- Article 20 on Information Sharing and the Biosafety Clearing House that mandates making available relevant information on biosafety, for instance regulations, decisions and assessments on or related to socio-economic considerations of LMOs. This activity on information sharing on is also directly connected to Article 26.2 on *“cooperation on research and information on any socio-economic impacts of living modified organisms, especially on indigenous and local communities”* (Secretariat of the CBD 2000:19).
- Article 22 on Capacity Building for cooperating in the development and strengthening human resources and institutional capacities for including, among others, socio-economic considerations in the decision-making process and effective implementation of the Protocol. The capacity building scope of Article 21 is directly related to Article 26.2 as well.
- Article 23 on Public Awareness, Education and Participation to which Article 26 is linked for: (a) The promotion and facilitation of public awareness and education on socio-economic considerations; (b) Participation of the public in the identification of socio-economic impacts; and (c) Valuation of socio-economic impacts in the decision-making processes.
- Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, particularly in relation to Article 12 on Civil Liability. Article 12.2 of the Supplementary Protocol mentions the alternatives that Parties could adopt in order to provide *“adequate rules and procedures in their domestic law on civil liability for material or personal damage”* (Secretariat of the CBD 2011b:7) on the conservation and sustainable use of biological diversity taking into account human health. Potential material damage may refer to any economic adverse effects that could result from changes in the biological diversity. Whereas personal damage could mean negative impacts on human health in the context of the CPB.

Based on this analysis, Article 26 has multiple interconnections with a wide range of provisions of the Protocol. Accordingly, it cannot be assumed as an isolated article.

## Conclusion

Article 26 of the Protocol is the recognition of the sovereign right of Parties to include, as necessary, socio-economic considerations for conserving and using sustainably biological diversity. Because biodiversity conservation and sustainable use (the core aims of the Protocol as well as of Article 26) are broad concepts involving all forms of life, their environments and their management, Article 26 is also inherently broad in scope. Additionally, the inclusion of socio-economic considerations arising from LMOs when reaching a decision of import of such organisms is not a marginal matter within the Protocol. This is because, Article 26 contributes to the objective of the Protocol: “[E]nsuring an adequate level of protection in the field of safe transfer, handling and use of [LMOs] [...] that may have adverse effects on the conservation and sustainable use of biological diversity taking into account human health” (Secretariat of the CBD 2000:3). In line of this, it is important to highlight that: (i) Consideration of human health in the context of biological conservation and sustainable use, as well as safe transfer, handling and use of LMOs are intrinsically social and economic processes; and (ii) Most national country decisions (e.g. such as import of LMOs) are taken upon socio-economic arguments (Khwaja 2002).

Certainly, along the implementation of the Protocol, socio-economic considerations cannot have a higher relevance than ecological issues, particularly more than conservation of biological diversity. However, their relevance cannot be neglected either since they are crucial for achieving sustainable management (or sustainable use, in the terms of the CPB). For this, the implementation of the Protocol would be incomplete, and not consistent with its objectives, if not adequately addressing socio-economic considerations when reaching a decision on import of a LMO.

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# Socio-economic Aspects in Decision-Making in the Context of the Biosafety Protocol: Malaysia's Experience and Case Studies

Letchumanan Ramatha and Johnny Andrew\*

**Abstract:** Socio-economic considerations are important components for careful decision-making to ensure that society enjoys the benefits of modern technology while minimising or avoiding its potential costs. However, in many parts of the world, information and analysis of the social and economic impacts of modern biotechnology are lagging behind. There is little experience in dealing with these issues in actual decision-making processes. The aim of this article is to highlight the provisions of the Cartagena Protocol on socio-economic considerations and to share Malaysia's experience in establishing a legal framework based on the Biosafety Act 2007 including designing and implementing policies and mechanisms that incorporate socio-economic considerations into decision-making as per the requirement under the Cartagena Protocol. The article also highlights experiences prior to coming into force of the Biosafety Act and the efforts made in institutionalising socio-economic considerations after the Act was enforced. Specific cases are presented where clear socio-economic considerations were taken into account in arriving at decisions.

**Key words:** Biosafety, biotechnology, Cartagena Protocol, LMOs, National Biosafety Board (NBB), Malaysia, GM crops, socio-economic considerations.

## Introduction

### *Provision in the Cartagena Protocol*

The Cartagena Protocol on Biosafety under Article 26 establishes the right of Parties to take into account socio-economic considerations arising from the impact of living modified organisms (LMOs) on the conservation and sustainable use of biodiversity in reaching a decision on whether to import LMOs especially with regard to the value of biological diversity to indigenous and local communities. This must be done in a manner consistent with the existing international obligations by which countries may be bound. While the Article provides a fairly limited set of conditions under which socio-economic considerations may be taken into account in

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decision-making regarding imports, countries may also incorporate socio-economic considerations other than those explicitly included in Article 26 into their domestic regulatory regimes on biosafety, as long as they comply with other international obligations. Under paragraph 1 of the Article, the Protocol appears to limit the scope of socio-economic considerations that governments may take into account in regulatory decisions to such circumstances as the impact of the import of LMOs on: (i) the continued existence and range of diversity of the biological resources in the areas inhabited or used by indigenous or local communities; (ii) the loss of access to genetic and other natural resources, as a result of biodiversity loss, previously available to indigenous or local communities in their territories; and (iii) the loss of cultural traditions, knowledge and practices in a particular indigenous or local community as a result of the loss of biological diversity in the community's territory. (MacKenzie *et al.* 2003)

Paragraph 2 of the same Article, however, encourages Parties to the Protocol to cooperate on research and information exchange on any socio-economic impacts of LMOs, especially – but not limited to – impacts on indigenous and local communities. Socio-economic considerations are relevant to domestic biosafety decisions and not just to transboundary movement of LMOs. In this regard, countries may incorporate into their domestic regulatory regimes on biosafety socio-economic considerations other than those explicitly included in Article 26, as long as these rules comply with any other international obligations by which they may be bound (Garforth 2004). At the same time, keeping to the spirit and letter of the Protocol, it could be prudent if Parties are to avoid disputes with their trading partners, such as complaints under the World Trade Organization (WTO). The WTO rules tend to emphasise decision-making procedures that rely on rules and regulations that center around scientific risk assessments, while limiting decision-making based on non-safety issues. The strict emphasis on scientific risk assessments under the WTO, are sometimes relaxed within implementation agreements, such as the Sanitary and Phytosanitary Measures agreement (Zepeda 2009).

## **Malaysia's Experiences**

### ***National Biological Resources***

According to the 2001 Global Diversity Outlook, Malaysia is one of 12 megabiodiverse countries of the world. Although Malaysia has only 0.2 per cent of the world's land mass, the diversity of its flora and fauna makes it one

of the richest countries in terms of biodiversity per unit area, as measured by the World Development Indicators. Notwithstanding that there is no definite data on the exact number of species in Malaysia, especially for small organisms such as insects and worms, a conservative estimate is that Malaysia has at least 170,000 species. With such rich biodiversity housed in a diverse habitats such as seas, rivers, swamps, mountains and forests, it is imperative that biotechnology products advance safely from the laboratory to field tests and are released to the environment without adverse impact on its biodiversity and the environment.

The National Policy on Biological Diversity, launched in April 1998, calls for the sustainable utilisation of our biological resources among others through biotechnology and the need to establish a legal framework on biosafety. For this reason, Malaysia signed the Cartagena Protocol on Biosafety on May 24, 2000 and subsequently ratified it on September 3, 2003.

### ***National Policy on Biotechnology***

The biotechnology sector including modern biotechnology has been identified as a new engine of growth for Malaysia as reflected in the National Biotechnology Policy 2005 (NBP) and the 9<sup>th</sup> (2006-2010) and 10<sup>th</sup> (2011-2015) Malaysian Plans. Under NBP legislative and regulatory framework development component, it aims to create an enabling environment through continuous review of the country's regulatory framework and procedures in line with global standards and best practices as well as developing a strong intellectual property regime to support research and development and commercialisation efforts.

Prior to the launching of the biotechnology policy there were very few research and development activities in modern biotechnology. In fact, it was mostly on the import of genetically modified (GM) grains for food, feed and processing. Since 1998, that is prior to the existence of biosafety law, all such applications were processed by an informal Genetic Modification Advisory Committee.

### ***Experience in Forming a National Legal Framework on Biosafety***

It was a landmark achievement for Malaysia when the Biosafety Act was passed by the Malaysian Parliament on July 11, 2007. The passing of the Act can be seen as a positive and promising beginning for Malaysia to take proactive approaches towards protecting human health and the environment from the possible adverse effects of the products of modern biotechnology as well as fulfilling Malaysia's obligation under the Cartagena Protocol.

Accordingly, the Act was enforced effective on December 1, 2009, two years after it was passed by the Parliament. This was followed by development of appropriate forms for application for release and notification for research works. As provided under the Act, and the understanding with stakeholders, the Biosafety (Approval and Notifications) Regulations 2010 was formulated and enforced effective November 1, 2010. The Act, Regulations, Application Forms and Institutional Biosafety Committee Guidelines form the key elements of the biosafety legal framework in Malaysia.

Consistent with the above framework, the National Biosafety Board (NBB), responsible for making decision pertaining to the release, importation, exportation and contained use of any LMOs derived from modern biotechnology, was formed in March 2010. The Chairman of the NBB is the Secretary General of the Ministry of the Natural Resources and Environment and its members comprise representatives from six other relevant ministries and four other persons with knowledge and experience in disciplines or matters relevant to the Biosafety Act. The Genetic Modification Advisory Committee (GMAC), consisting of experts from various science-based and other relevant disciplines working with the Government agencies, research institutes, private sectors and Non-Governmental Organisations to provide scientific, technical and other relevant advice to the NBB, was established in May 2010.

To operationalise the law and to support the NBB and GMAC, a dedicated department named the Department of Biosafety, was formed in May 2010, headed by Director General of Biosafety who is also the Secretary to the NBB. The Department also acts as a one stop centre for all activities relating to biosafety in Malaysia in addition to fulfilling its core functions, that is becoming secretariat to the NBB, GMAC and committees or sub-committees established under the NBB and GMAC.

In 2010, Malaysia, for the first time, made decisions on LMOs based on a proper legal framework, processes and appropriate procedures in place. As of July 31, 2012, the NBB had made decisions on eight applications on approval for release and twelve notifications on activities in contained environment (including the approval by informal GMAC).

### ***Provision on Socio-Economic Requirement in the National Legal Framework***

Consistent with the Cartagena Protocol under Article 26 which states, socio-economic considerations should be taken into account in implementing the national biosafety law, section 35 of the Malaysian Biosafety Act states:

“The Board or Minister shall not be prevented from taking a decision, as appropriate, under Part III or Part IV, where there is lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of living modified organisms or products of such organisms on human, plant and animal health, the environment and biological diversity and may also take into account socio-economic considerations.”

(Part III of the Biosafety Act refers to the approval process for release and import, Part IV to the notification process for export, contained use and import for contained use.)

It was not easy to get the industries to accept the provision on “may also take into account socio-economic considerations”. As more clarity was requested on these terms, the Biosafety (Approval and Notification) Regulations 2010 in section 25 on socio-economic considerations provides extended explanation as follows:

“The Board or the Minister, in taking into account socio-economic considerations pursuant to section 35 of the Act, may consider:

- a. the changes in the existing social and economic patterns and means of livelihood of the communities that are likely to be affected by the introduction of the living modified organisms or products of such organisms;
- b. the effects of the religion, social, cultural and ethical values of communities arising from the use or release of the living modified organisms or products of such organisms”.

### ***Considerations of Socio-economic Aspects in Decision Making***

Socio-economic considerations are important and sometimes even crucial in safeguarding the interests of indigenous and local communities in technology adoption. However, without clear parameters for the scope of socio-economic considerations of LMOs within the Cartagena Protocol, Malaysian uses the provision under section 25 of the Biosafety (Approval and Notification) Regulations 2010. The legal experts had great difficulty to include section 25 of the Regulations due to the possibilities of many interpretations of such a provision. It was clear then that this provision will have to be supported by some practical guidelines.

Socio-economic considerations can be taken into account in at least four different phases in biosafety decision making: during the development of a domestic biosafety regulatory regime; during the risk assessment for a particular modified organism; after a risk assessment – for example, during risk management, when decisions must be made as to whether identified

risks are acceptable; and during the appeal, review or renewal of a permit (Garforth 2004). The need for assessing the potential socio-economic impacts of LMOs is hinged on several important reasons including social responsibility, inter-generational responsibility, and social acceptance and reducing the long-term cost (Yoke Ling 2008). The assessment meanwhile can focus on three main elements: firstly, economic impacts such as distribution of benefits, research and development efforts by public institutions, labour, organic market, intellectual property right and control over the tools of production; secondly, social and cultural issues which include public opinion and impact to small holders; and finally, ethical considerations.

However, to date there are not many countries that have carried out socio-economic analysis for the consideration in the decision making about LMOs. Furthermore, socio-economic considerations in this regard is an area gradually emerging and will take a long lead time before a proper framework for economic analysis could be established. Thus, for the time being, it is likely that socio-economic considerations as are applied in other areas may be adopted as appropriately. In Malaysia, socio-economic considerations may become very important if the plantation industry of the primary commodities like oil palm, rubber, cocoa and others migrate into LMOs options of high productivity or high value added products at some stage. The small holders will then face problems of having to compete with plantations owners in selling their non-LMOs products. However, such problems may be resolved based on current experiences in related sectors.

In Malaysia, dealings with LMOs are mainly related to import of GM grains. So far the NBB has approved six types of grains. As these grains will not be able to grow in Malaysia, the possibilities of any socio-economic problems are quite remote. All approvals on such grain are imposed with appropriate terms and conditions including submitting regular reports of spillage and clear labelling of the product from importation down to all levels of marketing stating that it is only for the purpose of food, feed and processing and is not to be used as planting material. As corn is grown in some parts of Malaysia, growth of spilled GM grains during transportation may pose contamination though the probability is very low.

So far Malaysia has not come across any socio-economic situations in the conservation and sustainable use of biodiversity as highlighted by MacKenzie *et al.* (2003) as the country is still in its infancy in the development of modern biotechnology. However, with the fast

developments in biotechnology in other parts of the world, LMOs will continue to come into the country and the biosafety regulatory body in Malaysia will have to be vigilant to minimise impact especially with regard to the value of biological diversity to indigenous and local communities.

The consistently growing socio-economic problems arising from the increasing death cases caused by dengue fever from Yellow Fever Mosquito (*Aedes aegypti*) in Malaysia and in many parts of the world have facilitated the release of genetically modified mosquitoes and other genetically modified products like TMOF (Trypsin Modulating Oostatic Factor) to reduce the population of wild mosquitoes. In both cases, the release could also be supported by the fact that country may partly own the intellectual property right of the innovations.

In order to seek for more inputs on socio-economic consideration, it is important that a wider public consultation is carried out including through surveys. Though sometimes there may be multiple submissions on the same issue, particularly when some championing bodies are driving the submission, it would still be a worthwhile exercise to do as it may be able to identify a spectrum of issues and views. For example, a survey carried out by the Department of Biosafety in 2011 with about 1500 target participants indicated that more than 50 per cent supported the release of GM mosquitoes. Though it was a small survey, the result was useful to reflect that people are not completely against GM mosquitoes. This can be easily rationalised as those affected by death cases arising from Dengue would surely like to see the problems solved.

It is understandable that due to the nature of the subject, to include socio-economic considerations in the decision making based on detailed analysis is indeed difficult, time consuming and an expensive job. Parties have their sovereign right to decide what is appropriate to their society based on facts in hand. However, decision may be reviewed when new and credible information is made available.

### ***Setting up Socio-economic Committee under the National Biosafety Board***

Malaysia realises that in the future socio-economic issues may play an important role in the decision making on LMOs. As such it was recommended to the NBB that a Socio-Economic Committee is set up similar to the Genetic Modification Advisory Committee as the Biosafety Act provides for such an option. It is important that such a committee be established at the earliest possible time to enable members to build



their capacity in this area. However, as socio-economic issues can be very sensitive at times, and based on experiences in other areas such as environment, the NBB decided to set up just an informal advisory group. The Board is now hunting for experts from institutions of higher learning who are experienced in socio-economic analysis and who can be groomed in socio-economic analysis as applied to LMOs. The group when established and fully operational is expected to advise the NBB on request and on a case by case basis.

A synergetic event to the above was the launching of the National Bioethics Council (NBC) of Malaysia under the Ministry of Science, Technology and Innovation in May 2012 with the aim to provide advice, resolve and manage bioethical issues in the country. It was also aimed at promoting ethics in science and technology so that the development would not give contradicting impact on human and moral values, especially concerning the environment, social, health, culture, laws and religions. The council's main term of reference is mainstreaming bioethics and disseminating information on bioethical issues among people from all walks of life, including scientists. Although its general focus will be on technology applications and issues concerning stem cell, genetically-modified organisms, animal testing and synthetic biology, attention would also be given to integrity issues and matters constituting a conflict of interest. The council comprises experts from various disciplines related to bioethics, scientist and non-scientist, policy makers and stakeholders entrusted to collectively study the issues and challenges faced by the country in promoting new technologies. The establishment of National Bioethics Council opens a window for consultation by NBB thus complementing its effort. As this is a new set up, the working mechanism between the NBC and the NBB will have to be periodically reviewed to ensure effectiveness.

### ***Socio-economic Considerations for GM Mosquito and TMOF***

The following two cases are examples whereby the National Biosafety Board made their decision by also considering socio-economic aspects:

#### *i) Genetically Modified Mosquito (GM Mosquito)*

The National Biosafety Board on the October 5, 2010 made a decision to grant approval with terms and conditions to the application from the Institute of Medical Research (IMR) for a field trial to release transgenic male mosquitoes. This approval permits the release of male GM Yellow

Fever mosquitoes, *Aedes aegypti* OX513A(My1) strain and male non-GM *Aedes aegypti* mosquitoes (wild type) to conduct a field trial entitled “Limited Mark-Release-Recapture (MRR)” of *Aedes aegypti* wild type and OX513A(My1). The proposed release sites were in Bentong, Pahang and Alor Gajah, Melaka. The recommendation of GMAC to the NBB was for an approval with terms and conditions. Proper risk management strategies were to be followed as stipulated through the terms and conditions imposed. Additionally close monitoring is to be done to ensure that the terms and conditions imposed are implemented on the ground. Public consultation for this application was done in August 2010 for a period of 30 days. Concerns raised by the public were addressed and taken into consideration when making the decision. The basis of NBB decision is as follows which also include socio-economic considerations:

- The proposed field experiment is only for a limited small scale release and does not endanger biological diversity or human, animal and plant health when proper risk management strategies are followed as stipulated through the terms and conditions imposed with the approval.
- Risks identified for this field experiment were quite low in the context of a limited Mark-Release-Recapture field experiment. However, for a larger scale release, these risks will be re-evaluated.
- Only a small number of mosquitoes will be released in comparison to the existing wild population based on previous baseline population surveys conducted by IMR. In addition, the released GM mosquitoes have no selective survival advantage and will diminish through the process of natural selection.
- The proposed release site will be free from any dengue outbreak for at least three months before the start of the field trial and this will be verified by the relevant health authorities.
- Only male mosquitoes are released and male mosquitoes do not bite or carry the dengue virus. The Standard Operating Procedures for sorting the male mosquitoes for the release has been assessed and approved by GMAC. Sorting will be done mechanically, followed by a serial manual re-check on all the sorted mosquito pupae by three highly trained laboratory technicians of IMR.
- Upon completion of the field trial, responsible site management was imposed to ensure that the area is completely cleared of any released GM mosquitoes, that is the monitoring period was extended and also

additional fogging was to be carried out to ensure that there were no residue GM mosquitoes in the environment.

- The NBB, through the Department of Biosafety, was to closely monitor the implementation of the field trial to ensure compliance at every stage of the release.
- Science based issues or uncertainties highlighted by researchers well versed with the issue were taken seriously and included in the scientific assessment by GMAC.
- Some of the skepticism expressed through public consultation about the field trial was due to lack of understanding of the science behind the field trial and an assumption that it is the final release to suppress *Aedes* population. Other valid concerns were considered in the assessment.
- Residents from the field trial site will be engaged in public awareness activities and information about the field trial will be made available.

The following socio-economic considerations were also taken into account in the decision making:

IMR has been very actively involved in GM mosquito research since 2006. Previous studies have already been conducted as laboratory experiments (contained use) and semi-field trials. This field experiment is the next phase of this research and is also an important prerequisite for any subsequent full scale release for population suppression and an important aspect of its capacity building plan.

- Number of deaths and the cost of medication due to Dengue.
- New technologies should be explored to complement the integrated pest management programme (IPM).
- The suppression of *Aedes* population by incorporating this GM technology in the IPM is promising.
- Cayman Island has already done a field release of this GM mosquito and there were no issues caused by the release.
- Other countries such as United States of America (Colorado), Thailand, Brazil and India are involved at contained use experiments involving GM mosquitoes. Countries like Singapore and Vietnam are reviewing this technology involving GM mosquitoes. Malaysia too need to move with the time.
- A Malaysian agency has ownership in the intellectual property.

*ii) Trypsin Modulating Oostatic Factor (TMOF)*

The National Biosafety Board on July 26, 2011 granted approval with terms and conditions to an application from EntoGeneX Industries Sdn. Bhd. (EntoGeneX) for release activities of TMOF\_Yeast. This approval permits the release of the “heat-killed” TMOF\_Yeast containing TMOF (Trypsin Modulating Oostatic Factor) peptide which is formulated into Mousticide Rice-Husk (RH) and Mousticide Wettable Powder (WP). The products were aimed at controlling the *Aedes* mosquito larvae population. The recommendation of the GMAC to the NBB was for an approval with terms and conditions in accordance with the provisions of subsections 16(3) and 16(4) of the Biosafety Act for the use of Mousticide WP and Mousticide RH. This recommendation was based upon the condition that the issues identified in the environmental risk assessment be thoroughly reassessed for the accumulative impact from long-term usage of this product, or if TMOF is used for the formulation of another type of end product, as there may be variables in the effectiveness of the protocols used as well as variations in the risk exposure pathways. Proper risk management strategies are to be followed as stipulated through the terms and conditions imposed. These conditions include restrictions in distribution sites, such as finished, treated drinking water sources and also the imposition in mandatory labeling; for which product handling and safety instructions are to be clearly displayed. In addition to supporting data provided from studies done on the product, further studies shall be carried out, focusing on local organisms, in a prescribed period and the results reported back to NBB. Public consultation for this application was done from June 9, 2011 until July 8, 2011. Concerns raised by the public were addressed and taken into consideration when NBB made the decision.

The following socio-economic conditions were taken into account in the decision making:

- That impact studies of the product had already been conducted by the Malaysian Palm Oil Board on the oil palm pollinating weevil;
- That data had been provided in the Environmental Protection Agency (USA) report on the safety of the product. However, further studies have been imposed on the applicant;
- That the product is intended for use to control outbreaks of dengue fever, which is one of the critical health issues in Malaysia; and
- A Malaysian company has ownership in the intellectual property.

## Conclusion

Malaysia had its priority right to set up a working legal framework on handling living modified organisms. The Biosafety Act 2007 has been crafted with a small window on the possibilities of including socio-economic considerations in decision making. Though the Regulations 2010 has expended this consideration further, it seems it is still insufficient to create a framework of parameters for a comprehensive socio-economic analysis. Such being the case reasonable and practical approaches were taken for the inclusion of the same. Thus, the case studies serve as excellent examples of including socio-economics. However, terms and conditions imposed in the case studies should be closely monitored. Fast expansion in modern biotechnology and numerous challenges that are emerging necessitates the development of a simple framework for socio-economic analysis based on experiences in other areas. The approaches taken have made the Biosafety Act 2007 a workable piece of legislation.

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# Multiple Meanings, One Objective: The Case of Biotechnology Policy Convergence in Africa

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**Abstract:** Policy convergence, defined as the growth in similarity of policies over time, constitutes a central concept in comparative public policy, yet a great deal of ambiguity and contention surrounds it. The article discusses the conceptual and practical meanings of policy convergence in the context of efforts to harmonise biosafety systems across various regions of Africa. The article comes from a broader investigation of the ways in which three supranational organisations, the African Union (AU), New Partnership for Africa's Development (NEPAD) and the Southern African Development Community (SADC) are influencing processes towards the harmonised biosafety systems in southern Africa. Unearthing different stakeholders understandings of what convergence or harmonisation are, and how they can be achieved, the article argues that an illumination of the different framings of these concepts is crucial, not for the sake of eliminating differences between these understandings, but in order to illustrate the divergent realities and their potential to facilitate or inhibit policy making processes.

**Key words:** African Union, biosafety, biotechnology, harmonisation, New Partnership for Africa's Development (NEPAD), policy convergence, Southern African Development Community (SADC)

## Introduction

Many attempts have been made to create international protocols which facilitate the emergence of similar national systems for managing technologies, and a number of these efforts relate to biotechnology. The Cartagena Protocol on Biosafety is one mechanism that has sought to

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balance at a global level the risks and benefits of modern biotechnology (encompassing genetic engineering, tissue and organism cloning and genomics). Biotechnology is a pervasive technology, which brings together interests from many sectors, from the product development phase to the product marketing, utilisation and disposal phases. Management of this technology at the policy and regulatory levels is, therefore, inherently multi-level and multi-actor, and this brings both challenges and opportunities for policy actors. Across Africa, there have been many efforts since the early 2000s towards developing and implementing similar biosafety systems. There are many individual, institutional, sectoral, national, regional and international players in these efforts and their multiplicity and varying levels of involvement in the issue in space and time brings many dynamics to these efforts for the countries.

From an analysis of the ways through which three supranational organisations, the New Partnership for Africa's Development (NEPAD), African Union (AU) and the Southern African Development Community (SADC) are influencing cross-national biotechnology policy convergence or harmonisation processes in southern Africa, it was observed that there are different understandings of these concepts within various actor groups, with potential impact on progress towards the envisaged cross-national similarity in biosafety systems. The purpose of this article, therefore, is to advance and discuss the implications of these multiple and fluctuating understandings on progress towards policy similarity and on established theoretical perspectives within realms pertinent to policy studies such as systems, institutions, regimes, actor coalitions and networks.

Following this brief introduction, the rest of the article continues with an overview of biosafety processes in southern Africa, and then gives some theoretical perspectives on policy convergence followed by a brief overview of the data gathering methodology used. Empirical results are then presented, analysed and discussed, followed by some conclusions.

### **Biosafety Frameworks: From National to Regional Levels**

Biosafety, defined broadly as the safe application of biotechnology, is regulated at the global level through the Cartagena Protocol on Biosafety (CPB or the Protocol), which is a Protocol of the Convention on Biological Diversity (CBD). The CPB was adopted by the Conference of Parties to the CBD on January 29, 2000 (UNEP 2006). Even before the advent of the CPB, there were many efforts the world over to build regulatory and

technical capacity in countries for the development and enforcement of mechanisms for safe use of biotechnology. Policy development models used elsewhere in the world have been used by governments and organisations in developing countries in their process (e.g. the ISNAR and UNEP models and the African Union Biosafety Model Law, cf. Paarlberg 2000). Completion of policy development has been slow though. Looking specifically at southern Africa, only five out of the 15 countries in the SADC region have managed to put in place functional biosafety systems in the last 10 years (Mumba<sup>1</sup> personal communication 2007; SADC 2004; NEPAD-ABNE 2012). These five are South Africa (1997), Zimbabwe (1998), Mauritius (2002), Malawi (2003) and Zambia (2007). The other countries either have advanced drafts of legislation which are being discussed or are nearing discussion at parliament level (Namibia, Tanzania, Botswana and Swaziland) or still have draft guidelines and other preliminary documents being developed by committees of experts set up by government (Lesotho, Mozambique, Congo DR, Seychelles and Angola) (see Omamo and von Grebmer 2005; NEPAD-ABNE 2012). Even within each category, the countries do not necessarily have the same policy and regulatory arrangements, and they have employed different approaches and mechanisms to attain that particular status, and the lengths of time and amount (and type) of resources<sup>2</sup> spent to achieve this also differ.

The challenges that countries face in developing and implementing effective biosafety systems include perennial lack of prioritisation of biosafety issues in national agendas, lack of financial resources and trained manpower or expertise in the field of biotechnology, as well as limited awareness and consensus on biotechnology issues among policy makers, lawyers, scientists and the general public (Mugwagwa 2011; NEPAD-ABNE, 2012<sup>3</sup>). The limited number of active research programmes employing modern biotechnological techniques in the majority of the countries has also been seen as a hindrance to the development of national policies and regulations. In other words, there is a lack of adequate technological developments to act as a catalyst for development of regulatory mechanisms (Ushewokunze-Obatolu 2004 Jaffe 2006).<sup>4</sup>

While all these developments are going on at national level, there has also been a number of initiatives towards convergence or harmonisation of biosafety systems in Africa, both at the continental level and at sub-region level. These initiatives are inspired by the Cartagena Protocol which sets global rules and regulations on the transboundary movement, transit,



handling and use of living (genetically) modified organisms. The AU developed the African Model Law on Safety in Biotechnology which was finalised in 2001, while the SADC developed a regional framework on safe handling and transboundary movement of GMOs in 2007 (see also SADC 2003). The NEPAD promotes cross-country cooperation and co-evolution between technologies and policies in its *Freedom to Innovate* report (Juma and Serageldin 2007) and the African Consolidated Plan of Action for Science and Technology (NEPAD OST 2006). Meanwhile, some countries from the SADC region participated in the Global Environmental Facility/UNEP Biosafety Project whose different phases had different but complementary and cumulative objectives hinging on promoting information sharing and collaboration, especially at the regional and sub-regional levels and helping countries comply with the CPB. There other players whose activities aid in the thrust towards a harmonised/converged regional biosafety system include the Common Market for Eastern and Southern Africa (COMESA)<sup>5</sup>, various regional and local-level civil society organisations.

Cross-national similarity of biosafety systems is seen as desirable from economic, regulatory, technological and environmental view-points, with expectations that it will allow countries to share resources, draw lessons from each other, and shorten technology and product approval processes and also positively impact on the environment conservation efforts of countries (Ayele 2006). However, the motivations and compelling factors for policy convergence and harmonisation from international and national perspectives are always fluctuating, and this presents challenges to the feasibility of the convergence/harmonisation agenda.

### **Theoretical Perspectives on Cross-national Policy Convergence**

Policy convergence is broadly defined as the growing similarity of policies over time (Bennett 1991; Kerr 1983; and Knill 2005) and policy convergence studies are thus concerned with the similarity of policies as an observable phenomenon. Policy diffusion, transfer, learning and harmonisation are viewed as pathways or mechanisms towards convergence. Scholars in these areas are in agreement on this (see review by Heichel *et al.* 2005). It is however, acknowledged that convergence may be a result of other problem pressures and not necessarily the ones mentioned above (Knill 2005). In addition, similarity, which is the main concept fundamental to convergence research, is viewed as arbitrary and ambiguous. Sartori (1991) argues that being “similar or different is a matter of degree and the cut off point can be set arbitrarily”. These ambiguities manifest themselves in

many ways, including how the convergence can be achieved and how to define the convergence.

According to Holzinger and Knill (2005), the first studies in the area of cross-national policy convergence date back to the 1960's, although the topic itself gained further popularity in the 1990s. The growth in international trade and commerce brought about by developments in technology in the last fifteen to twenty years – commonly referred to as globalisation - has been mentioned as the major reason behind the increased interest in cross-national policy convergence studies (Faria 2002). The 1990s also mark the period in which issues on European integration came to the fore, with a number of researchers investigating the domestic impact of the Europeanisation drive and cooperation of European countries on matters of biosafety, and also the 'transatlantic' issues (see Holzinger and Knill 2005; Murphy and Levidow 2006; Wield *et al.* 2004).

Studies on policy convergence have been carried out in many policy areas, most extensive of all being on social policy, fiscal policy, environmental policy and trade policy. There have also been some, but fewer studies on health policy, migration policy, agricultural policy and education policy (Heichel *et al.* 2005). With respect to biotechnology and biosafety, some studies have examined harmonisation in the EU (see Levidow *et al.* 1996). In their review of empirical studies on policy convergence, Heichel *et al.* 2005, also note that while the number of policy areas covered is fairly broad, a major limitation has been in the geographical regions covered by the studies. The majority of the studies have been carried out in Europe and North America, with very few being carried out in Latin America, Asia and Africa. They attribute this to lack of available data and also to the heightened interest in Europeanisation and globalisation issues which are easier to examine in integrated markets. The authors acknowledge that it is 'still not possible to characterise convergence research as a global phenomenon because [researches on] Africa and Asia, for example are still underrepresented ...'. Even some of the key people championing convergence efforts in Africa have acknowledged the lack of academic input in the various processes taking place (John Mugabe<sup>6</sup> personal communication 2007). There is thus a need for processes towards convergence of biosafety systems in Africa to be studied and analysed. This will enable fuller and more detailed insights into these processes and empirical evidence from Africa to contribute to this growing field of convergence studies as well.

Convergence is generally accepted to be a result of many mechanisms which include harmonisation, coercion, diffusion and policy transfer (Jordan 2005; Holzinger and Knill 2005; Busch and Jorgens 2005; Seeliger 1996). The main limitation in current literature on convergence research is that most of the work has focused on single mechanisms. The typology proposed by Busch and Jorgens is an attempt to look at a combination of mechanisms and to provide a framework to explain the multiple understandings and interpretations of the phenomenon. Lehtonen (2006) applied this typology to the environmental performance reviews (EPRs) carried out by the Organisation for Economic Cooperation and Development (OECD) in its member countries. He found the typology useful and he concluded that the mechanisms in operation, which are mainly social learning, socialisation, persuasion and soft coercion, are dependent on the fact that the OECD is an organisation without direct regulatory power; and also on the existence of environmental change agents in the member countries. Application of this typology on biosafety issues in the SADC region, therefore, promises to provide new insights.

A look at the reasons for, and implications of existence of multiple interpretations of convergence is an important component of the quest to understand the convergence processes. This is because from the onset, the divergent understandings and perspectives represent essentially why there is need for convergence in the first place. This is akin to the rationalist notion that 'problems create the incentives for their solution' (Haas 2004). Like many other policy arenas, the biotechnology or biosafety arena has a wide range of issues and it is hardly conceivable for there to be an organisation with the mission and resources to be able to tackle all the pertinent issues. As Haas (2004) explains:

"the efficiency gains from relying on one single source of policy advice are more than offset by the loss of legitimacy, analytic blinders imposed by relying on just one institutional source ... and the political doubts of bias ...".

Divergent views are thus inevitable and represent the reality on the ground. The purpose of this analysis is to situate the theory and the practice within the realities in order to enable an evidence-based decision formulation process. One main interest is to understand how achievable the convergence agenda is in the context of these divergent understandings, and at what cost to the holders of the different perspectives. All this takes place in the backdrop of an understanding that stakeholders pressures influence policies (cf. Chataway *et al.* 2006).<sup>7</sup>

## Methodology

The different meanings associated with convergence were identified largely based on an analysis of documents from various organisations taking part in efforts towards development of converged systems. Responses from interviews conducted among stakeholders in the SADC region and beyond as part of the bigger study were also carefully analysed for the different framings of convergence.<sup>8</sup> An evaluation of both the formal and informal discourses<sup>9</sup> on biosafety and in the broader science and technology arena was carried out in order to gain a wider understanding of the issue. One of the main difficulties with this task is that in their day-to-day work on biosafety issues, stakeholders hardly refer to their work in convergence terms, and in some cases biosafety is not a prominent issue on the day to day policy agendas. However, it is for these reasons that an understanding into the various conceptual and practical meanings of convergence was sought. Data analysis was done using thematic analysis (Boyatzis 1998), with *meanings of concepts* being one of the themes.

## The Emerging Understandings

USING discussion and interview results and observations from the interactions with stakeholders, a compilation of different meanings or accounts of convergence was developed. The understandings have been classified according to a number of factors (see Table 1).

The different understandings in Table 1 represent various dimensions of issues around convergence; among them being what should converge, who should be involved in the processes towards convergence, where should convergence take place, how should convergence take place and why should convergence take place? The characterisation as broad versus narrow or process-based versus output-based perspectives of convergence is based on the different opinions or responses to these clusters of questions. Narrow-focused understandings are defined as those looking at convergence of regulations only or the practice within the technology only, while the broader understandings cover both the technology, the regulations and pertinent issues in allied areas such as seed laws and intellectual property rights. Narrow-focused understandings also propose limited time scales and geographical scope with respect to feasibility of convergence. Process and output-based accounts, on the other hand, relate to the different ways of achieving convergence (the process) and the resultant policy or regulatory arrangements (the outputs). Many issues emerge from this typology and also from the perspectives behind this representation, and these will be looked at more closely.

**Table 1: The Different Understandings/Framings of Convergence as Observed From Stakeholders**

Description	Scope	Main stakeholders behind understanding	Categorisation (Broad or Narrow focus)	Organisation where particular focus is dominant
<b>Output-focused<sup>10</sup></b>				
Convergence on biosafety and allied issues	Risk regulation, Technology development	Scientific R&D institutions	Broad focus	NEPAD
Convergence on biosafety only	Risk regulation	Polymakers, food relief agencies/civil society organisations (CSOs)	Narrow focus	AU, SADC
Convergence with respect to risk assessment only	Risk regulation	Polymakers, food relief agencies/CSOs	Narrow focus	AU, SADC
Implementation at regional level	Collaboration with neighbouring countries	Regional bodies, scientific R&D institutions	Broad focus	AU, NEPAD
Implementation at national level	Focusing on serving national interests	Relevant government departments	Narrow focus	SADC
<b>Process-focused<sup>11</sup></b>				
Co-evolution of technology and regulations	Risk regulation, Technology development	Regional bodies, scientific R&D institutions, relevant government departments	Broad focus	NEPAD
Convergence on regulations only	Risk regulation	Polymakers, food relief agencies/CSOs	Narrow focus	AU, SADC
Involve policy makers only	Focus on the top	Policy makers, food relief agencies	Narrow focus	SADC
Involve all key stakeholders	Broad stakeholder consultation	CSOs, some government departments	Broad focus	NEPAD
Stepwise in terms of geographical and institutional coverage	Structured and bottom-up focus	Regional bodies, R&D institutions, policy advisers	Narrow focus	All three reflect this at certain stages
Holistic and all-encompassing approach through and through	Combinations of approaches	Regional bodies, R&D institutions, policy advisers	Broad focus	As above

The distinctions between the broad against narrow (or process versus output-based) accounts with respect to the responses to the clusters of issues above are not as clear-cut as shown here, and this is due to a number of reasons. The following are some of the reasons behind the different and fluctuating framings:

### **Unclear Understanding of Terms**

On one extreme, there are policy actors who do not seem to fully understand the meanings of the terminologies they use and the differences between them and other related terms. One researcher from a scientific and industrial research and development institution in Zambia indicated that he “was confused as to whether what is required is consensus, unanimity or coherence ...”, though he “felt the desired end is to have regulatory systems that speak to and understand each other”. He also bemoaned the lack of arrangements to introduce and equip policy actors adequately to deal with challenges in the policy innovation arena. This is a serious problem in some cases and one of the reasons could be what Alvin Weiberg observed in 1972 about scientists “[that] often they were asked to provide advice that exceeded their formal disciplinary training” (cited by Haas 2004). There is thus an issue of actors facing the challenge of moving, for example, from being policy implementers to being policy developers, without the necessary exposure and experience.

On the other extreme, there are some policy actors who get locked into certain framings and understandings, mainly to be seen to be in sync with current discourses, and to be able to secure funding from donors. This is particularly the case with process-based accounts. For example, multistakeholder or participatory processes seem to be the mantra for civil society-driven processes, and whether or not this brings the required efficiency may be quite another issue. The following observation in August 2006 from one coordinator of a regional biodiversity programme in the SADC typifies this dilemma:

“Let’s not forget that there are two key issues here; the problems exist here, but they are identified (from) elsewhere, and the agenda to address them is set elsewhere too. So we have to comply ... with the problem-packaging and the solution-packaging.”

### **Rivalries, Alliances and Organisational Mandates**

Contested power, competence and legitimacy issues between and among institutions also lead to some institutions and/or individuals wanting or

adopting certain framings at the expense of others. The same is also true where institutions want to identify with the practices in another institution, to the extent of adopting similar practices. There are thus understandings based on rivalries or alliances among institutions. For example, two leading supranational organisations have had their staff failing to attend meetings of the joint committee set up by these two organisations because of the fundamental conceptual differences between the two organisations. A respondent from one of the institutions was very emphatic that: “... *this joint committee is just a requirement of the donors, otherwise we have no [further] grounds on which to cooperate*”.

The mandates and missions of different institutions have a major influence on how they frame the convergence issue, and this in turn depends on the actor coalitions around each institution and the issue at hand. Fluctuations within the actor coalitions sometimes result in fluctuations in framings. Further complications on this emanate from the fact that the different actors are at various vertical and horizontal levels, ranging from institutional, sectoral and national to international levels.

### **Varying Demands on Convergence of Ideas**

The level of interdependence among institutions varies considerably in space and in time, and this leads to constant shifts in the understandings. For example, in international fora (e.g. negotiations and discussions under the Biosafety Protocol) organisations that are ordinarily rivals within the region may be forced to present a unified agenda, and this causes a temporary, though sometimes permanent shift in the understanding. On the other hand, allied institutions may present divergent faces as a way of trying to develop some unique selling points for their programmes. One respondent from a policy analysis network in the SADC region indicated that:

“when all factors have been taken together, our agendas and the way we discern and implement processes is influenced more by providers of funding, than by the local policy communities we intended to serve ... our own visions vary with those of the providers of funding.”

Early 2006 saw southern African partners on both divides of the biotechnology debate participating in a preparatory meeting for the Cartagena Protocol on Biosafety's Conference of Parties (COP) which was held in Brazil. The coming together in the preparatory meeting was possible because, as one senior official in a regional biodiversity management programme observed:

“...a donor came along and gave the region funds to prepare that way so that a regional voice could be developed’ ... but ‘... as it turned out, when we got to Brazil, everyone teamed up with their traditional international partners ...”

## Resources

Linked to the issue of mandates and missions, is the issue of resources for implementing programmes. Many organisations and programmes have to contend with a narrow remit of issues because of restricted resources. Resource availability thus dictates how stakeholders or clusters of stakeholders should understand an issue, in the process influencing what is deemed feasible. It is argued that availability of resources can propel development towards a common pattern despite disparate politics, ideology and culture (McGaughey and Cieri 1999). In fact, respondents highlighted the issue of resources as both the biggest hurdle to, and determinant of the potential path to be taken by policy processes.

## Mobility of Policy Actors

Then there is the issue of policy actors moving from one policy arena to another, either in pursuit of new employment opportunities, or as part of the routine ‘surfing’ to fill capacity gaps (cf. Hilgartner and Bosk 1998). This not only leads to a continual fluctuation of the understandings of the issue among groups of actors, but further blurs the distinctions between the different categorisations of understandings. Policy actors also find themselves not having enough time to adequately prepare for, or consider issues, as one respondent from a national farmers’ union indicated:

“...being in this position can be distressing sometimes, as I have to deal with many issues, from HIV/AIDS, climate change, pollution, and then this (biosafety and biotechnology). And I have to represent my organization on all these issues. Coping with the demands is never easy, especially keeping up with the latest developments. Half-baked jobs are the order of the day.”

In addition to the above challenges emanating from capacity constraints, there are country-specific conditions that influence understandings towards certain policy positions/conceptualisations. Appreciation of these drivers is crucial for shaping interventions within the multi-actor arena. For example, there are countries which have a long tradition of being risk-averse (e.g. Zambia<sup>12</sup>) and always waiting for technologies to mature before they can take them on board. Such countries are, not surprisingly, more towards the narrow, country and biosafety-centric measures. A country’s or an



institution's capacity to create, acquire, accumulate, diffuse and utilise scientific knowledge also has a strong correlation with the breadth of their understanding of the issue, although the leadership influence of some countries and institutions may have a confounding effect.

### **Linking Back to the Technology**

The scope of issue framing within the technology arena also influences how policy convergence is framed. Schattschneider (1960) discusses policy entrepreneurs engaging in 'venue shopping', that is, searching for arenas from which to frame policy problems, and that the policy entrepreneurs may themselves 'limit the venues in which they set their feet'. For example, taking science only as a policy venue, the leeway for venue shopping is likely to vary across countries, across other sub-national arrangements, and among policy actors (Renn 1995). Different actors may seek access to different types of venues (Pralle 2003), and this illuminates how public problems are a result of successful imposition of problem definitions by one group on others (Hajer 1995). In the SADC region, for many policy actors, biosafety is about safe application/use of products of modern biotechnology, while to others, it is about ensuring safety of all 'biological' processes and products (Kelemu *et al.* 2003). Science and scientific knowledge are key venues in both cases, but the extent to which these are explored and incorporated in the science-policy nexus differs because of the different levels of focus on the science. These different framings result in what Schattschneider referred to as issues being "organised into or out" of politics. In the final analysis, this has a bearing on both the process-based and the output-based accounts of convergence.

### **Analysis and Interpretation of the Emerging Understandings**

This issue of cross-national policy convergence, looking specifically at biosafety in the SADC region, looks into a number of practical and theoretical perspectives around convergence. These include international relations, organisational and institutional theories, coordination theories (for example, the game theory model) and systems theory, among many others. This essentially reflects the broad, all-encompassing and integrative nature of biotechnology/biosafety issues, and the various forces at play in the social construction of public problems. However, this analysis has narrowed down to a few perspectives given the main force behind these multiple understandings, that is, the movement of actors within the policy arena. These understandings are also being influenced by the issue

of resources, and the expectations of resource inflows as well as speedy implementation of activities which are stimulated by how the issue is framed.

One issue that seems to emerge in practice as a result of these multiple understandings is the proverbial “too many cooks ... spoiling the broth”. This manifests itself in a number of ways, for example, some aspects within the full integrative range of issues around biosafety are left unattended as actors jostle to occupy arenas that attract funding, and from which they can easily make an impact. This is why, for example, many organisations tend to occupy the information dissemination arena where it is easier to leave a mark. Concurrently, the same organisations will be looking around and believing that someone among the many other players will take up the remaining issues. A number of gaps also exist within both the vertical and horizontal dimensions of the issue (Shaffer and Pollack 2004). Often this is not because the information or other attributes to fill those gaps are not there, but because of a lack of obligation among the various players to take forward what the player at the other level (lower or higher) has done. This issue is best explained within the social arena of problems (cf Hilgartner and Bosk 1998), where multiple perspectives may not overlap enough to cover the issue area adequately.

While talking about the teaching of the so-called new and ‘authentic science’ (as opposed to traditional science), Roth (2001) alludes to enculturation that may lead to the acquisition of conceptual blind spots and prejudices as a result of trying to get students “to do the real stuff”. The desire to want to “move with the time” with respect to issues within the discourse on a given issue sometimes leads to an exclusion of other key considerations, leading to poor delivery at the end of the day. Ray Dart<sup>13</sup> (2006) also talks about such blind spots in the non-profit strategy process, where emphasis is placed on organisational and programme strategy, leaving out change models and intervention strategies. It is crucial that when the different understandings of convergence are brought together, such blind spots are minimised.

The public arenas model on the rise and fall of social problems (Hilgartner and Bosk 1998) looks at the issue of stakeholders “jumping” from one policy domain to another, and also how dramatisation is crucial in getting a policy issue to attract attention in the midst of competing interests. These perspectives are crucial in explaining and understanding what is happening in the issue at hand, and in devising an appropriate way

forward. In biosafety the particular challenge is on how the issues come together at regional level, bearing in mind that the dynamics are different from those at national level. There is problem amplification beyond predictable levels. Issue novelty and policy arena saturation dynamics also vary as different jurisdictions are brought together. This inevitably leads to different understandings of the issue at hand. The public arenas model of looking at the rise and fall of social problems can thus provide useful insights in the dynamics of framing the biosafety policy convergence problem. One of the key questions, therefore, remains how one dramatises an issue which is at different agenda levels in space and time, ensuring consistency of meaning at the different levels.

There is also a wave of expectations created around the different issue framings. A combination of the framings and the new technology creates an even higher sense of expectation amongst the intended beneficiaries of the planned interventions. Expectations play a crucial role in resource mobilisation and galvanising actor groups (Borup *et al.* 2006). It is, therefore, important that these different understandings, and the expectations they elicit among stakeholders are understood, so that the envisaged purpose of bridging or mediating across different actor boundaries and levels can be better managed. It is also important to note that some kind of a prisoner's dilemma exists amongst the different stakeholders and the interpretations that they hold. Stakeholders are not sure what impact their independent pursuit of self-interest (that is, their framing of the issue and the attendant implementation mechanisms) will have on the bigger policy community of which they are only a part. As a result, actor communities may find themselves undecided on what route to take given the various and fluctuating forces around the issue. Consultation among the different stakeholders and feedback on their interpretations of the policy process are, therefore, crucial in building synergies.

## Conclusion

The article has highlighted that what may appear to be mere differences in semantics, or different expressions of the same desire, may in the long run have telling impacts on how "visions" or "imaginings" can be translated into tangible outputs at the policy level. In the final analysis, therefore, the challenge is to try and understand the ways in which these fragmented perspectives may eventually come together towards the envisaged collective action. In other words, is it possible for convergence to occur

in the backdrop of multiple understandings of convergence? This has an implication on how the convergence can be achieved, and how sustainable the converged systems will be. Do the different understandings at some stage have to pave way for a consensus position?

Social constructivists have shown that “various actors are likely to hold different perceptions of what the problem really is”. However, as Hajer (1995: 44) alludes to in an analysis of discourse around environmental dilemmas, it is important to ‘understand why a particular understanding of the environmental problem at some point gains dominance and is seen as authoritative, while other understandings are discredited.’ While the article has presented and analysed the different ways in which the biotechnology policy convergence problem is presented, and the emergence of social coalitions around specific understandings, the issue of how coherence emerges from these differences is an important subject in its own right. The social-constructivist rejection of the “single problem-single answer” model (Hajer 1995:43) is key in understanding how the various perceptions then come together.

Knowledge of the different understandings of convergence is crucial, not for the sake of eliminating differences between these understandings, but in order to present evidence of these existing realities to the policy making process. The prevailing understandings of policy convergence in biotechnology or biosafety in southern Africa region are influenced by a number of issues ranging from organisational institutional missions and mandates, organisational and individual capacity issues, resource-related issues, and the ever-present challenge of legitimacy which confronts policy processes. This discussion has looked at how these issues are at play and how it is in the best interests of both policy actors and researchers to understand the context as a way towards ensuring a better link between policy discourses and practice.

## Endnotes

- <sup>1</sup> Prof. Luke Mumba is the Director of the Southern African Network on Biosciences (SANBio), one of the four subregional networks for the NEPAD’s African Biosciences Initiative (ABI).
- <sup>2</sup> Resources here include policy/legislation models used as well as the common financial, human and other material resources.
- <sup>3</sup> <http://www.nepadbiosafety.net/for-regulators/resources/subjects/biotechnology/status-of-crop-biotechnology-in-africa> (accessed September 14, 2012)
- <sup>4</sup> This techno-centric view is shared by many scientists in the region, while those less optimistic, notably anti-biotech lobbyists feel the issue needs to be looked at within the bigger macro context of individual countries and the region.

- <sup>5</sup> COMESA and its partners are currently at advanced stages in the development of a regional biotechnology policy to guide decision-making on commercial planting, trade and GM-food aid. (ISAAA, May 2012: <http://www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=9602>)
- <sup>6</sup> Prof. John Mugabe is a former Director/Advisor of the NEPAD Office of Science and Technology.
- <sup>7</sup> Stakeholders 'loyalty' to policy agendas when their issue framing is ignored or sidelined is part of the investigation in the bigger research.
- <sup>8</sup> The respondents included regulators/policy makers, NGO workers, scientists, research managers/administrators, representatives of international development partners and staff from the three supranational organisations. Study was conducted between 2006 and 2008, with further data being collected in 2010 and 2011.
- <sup>9</sup> 'Formal' refers to discussions or issues raised while respondents were speaking in their official capacities (e.g. in meetings/workshops, interviews, etc.) while 'off-the-record' or personal views and other opinions outside the official setting are referred to as 'informal'.
- <sup>10</sup> Referring to the policies/regulatory systems.
- <sup>11</sup> Referring to the path being followed to come up with the policies or regulatory systems.
- <sup>12</sup> As indicated by one respondent from a news agency in that country, and echoed by a scientist from a national research institution.
- <sup>13</sup> Ray Dart, Paper Number PA061238, Trent University, Peterborough, Canada.

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# Socioeconomics, Biosafety, and Sustainable Development\*

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**Abstract:** Article 26 allows Parties to take into account socio-economic considerations in biosafety decision making. This opens up the possibility bringing biosafety closer to sustainable development. An integrated consideration of environmental protection, and, economic and social development can facilitate this. This article discusses the relevance of emerging principles of sustainable development law in this.

**Key Words:** biosafety, precautionary principle, Agenda 21, Cartagena protocol, socio-economic considerations

Biotechnology, particularly plant and animal biotechnology, is perceived differently by different cultures because of different assessments of its prospects and its ethics.<sup>1</sup>

Many people, societies and States express concern over the social and economic changes that will accompany the widescale use of biotechnology and its products. It is not a visible part of the international development agenda primarily because of the controversy surrounding the potential risks of living modified organisms (LMOs) to biodiversity and human health, as well as the potential relevance of LMOs for traditional farming sectors in developing countries.<sup>2</sup>

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Chapter 16 of Agenda 21 on the environmentally sound management of biotechnology provides the following context:

Like with most new technologies, research in biotechnology and the application of its findings could have significant positive and negative socio-economic as well as cultural impacts. These impacts should be carefully identified in the earliest phases of the development of biotechnology in order to enable appropriate management of the consequences of transferring biotechnology.<sup>3</sup>

As a result, many countries that are adopting biotechnology insist on using a decision-making process that looks beyond the narrow range of impacts covered by the scientific risk assessment of a specific LMO. Deciding what is right or permissible in relation to biotechnology in many contexts requires bringing together the knowledge established by a scientific risk assessment of an LMO with socio-economic information on that society and its culture. This is a reflection of the fact that when considering the use of new technologies, scientific, ethical, and social issues cannot be wholly separated from one another.<sup>4</sup> Socioeconomics, as a discipline, begins with the assumption that economics is not a self-contained system but is embedded in culture, government, and society. It does not assume that interests are necessarily complementary and harmonious, and recognises that societal sources of order are necessary for markets to function efficiently. It also recognises that individual choices are shaped by values, emotions, social bonds, and moral judgments rather than presuming that people act rationally or pursue only their self-interest or pleasure.<sup>5</sup>

The Cartagena Protocol allows Parties to take socio-economic considerations into account in biosafety decision making through Article 26, which reads:

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.
2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.<sup>6</sup>

Biosafety risk assessment, described in greater detail in Chapter 4, aims to ensure that decisions about policies and activities pertaining to the development of biotechnology are taken with an understanding of the potential adverse impacts to the conservation and sustainable use of biological diversity, as well as risks to human health. In this light, socio-economic information is needed to provide a more complete picture of the impact of biotechnology. An assessment of environmental, social, and economic impacts in biosafety decision making would be more consistent with the sustainable development principle of integration and interrelationship of social, economic, and environmental objectives.<sup>7</sup>

Application of the principle of public participation, discussed in greater detail in Chapter 7, in this context suggests that a country's policy about the use of biotechnology ought to be determined in consideration of the views and participation of a well-informed public.<sup>8</sup> Such an approach is reflective of responsive, transparent, and accountable governance and is informed by the human right to hold and express opinions and to seek, receive, and impart ideas; the right to access appropriate, comprehensible, and timely information held by governments and commerce on economic and social policies about the sustainable use of natural resources and the protection of the environment; and the right to access to effective judicial or administrative procedures to challenge unsatisfactory decisions and seek compensation.<sup>9</sup>

The inclusion of socio-economic considerations in the Cartagena Protocol allows for the creation of a decision-making process for biosafety that can be tailored to a broad range of States, societies, and cultures, so long as the measures taken are consistent with its other international obligations. It is also reflective of several sustainable development law principles, such as integration and interrelationship, common but differentiated responsibilities, the precautionary approach, public participation, and good governance.<sup>10</sup>

This chapter focuses on Article 26 of the Cartagena Protocol, fleshing out its meaning through its negotiating history, potential role in biosafety decision making, and the precepts of sustainable development law. The first section discusses the negotiations and the legal text of Article 26. The second section considers the role of socio-economic considerations in biosafety regulatory regimes. The third section describes the nature of socio-economic considerations in light of the principles of sustainable

development law. The chapter concludes with a discussion of how the use of socio-economic considerations in biosafety could be promoted as a tool to support sustainable development.

### **Socio-economic Impacts and Biosafety**

Negotiations on biosafety following the entry into force of the Convention on Bio- logical Diversity (CBD) brought up many differing views on the socio-economic impacts of LMOs and considerations relevant to biosafety decision making. At the first meeting on biosafety under the aegis of the CBD, the 1995 Madrid Group of Experts on Biosafety, no consensus could be reached between Parties on whether socio-economic considerations should be a part of biosafety decision making.<sup>11</sup> With the receipt of the Madrid Group's report, the second Conference of the Parties to the CBD (COP 2) launched the Open-ended Ad Hoc Working Group on Biosafety (BS-WG) to negotiate a protocol and where socio-economic considerations would be discussed further.

At the first meeting of the BS-WG (BS-WG 1), most developed countries argued that socio-economics had little place in biosafety decision making and that including such considerations in the Protocol was not worthy of further study.<sup>12</sup> Many developing countries disagreed, because they believed that "in addition to economic impacts such as income distribution, the negative socio-economic impacts of LMOs could include erosion of agricultural and other biological diversity; risks to sustainable use of existing biodiversity; and the threats of transgenic animals and plants to the cultural and religious order of some countries."<sup>13</sup> The outcome of BS-WG 1 was a request that the Secretariat prepare a bibliography on both the positive and negative socio-economic impacts of biotechnology for consideration at the following meeting.<sup>14</sup>

At BS-WG 2, the bibliography prepared by the Secretariat was considered alongside the written submissions of governments. The African Group proposed the most comprehensive provisions on socio-economic factors, which were incorporated into the draft provisions on objectives, general obligations, notification, risk assessment and management, and liability and compensation. The African Group's draft article on socio-economic considerations noted the time before impacts are felt and proposed a seven-year notification period prior to the export of LMOs, while also containing an extensive list of considerations for risk assessment. This list included anticipated changes in existing social and economic patterns; possible threats to biodiversity, traditional crops, or other products; impacts

caused by the replacement of traditional crops, products, and indigenous technologies through modern biotechnology; anticipated social and economic costs resulting from loss of genetic diversity, employment, market opportunities, and the livelihoods of communities; disruptions to social and economic welfare; and possible effects contrary to the social, cultural, ethical, and religious values of communities.<sup>15</sup> Bolivia's submission noted that the sustainable use of biodiversity, particularly domesticated plants and animals, depends on the socio-economic conditions of the people who have developed and conserved them for generations, and that the introduction of genetic engineering technologies and LMOs into countries with rich biological and genetic diversity can result not only in the depletion of that diversity but also threaten the economic situation of people who rely on biodiversity, which could lead to discontinuation of the traditional agricultural systems and a loss of genetic diversity.<sup>16</sup> On the other hand, Canada, the European Union, and Japan all weighed in against addressing socio-economic considerations in the Protocol.<sup>17</sup>

Governments submitted draft text prior to BS-WG 3 and the submissions of the African Group, Cuba, India, Madagascar, Malaysia, and Sri Lanka all included reference to socio-economic considerations.<sup>18</sup> It was agreed at that time that socio-economic considerations would not be further researched, but rather included in the consolidated text of draft articles with the texts already submitted by governments set out as options.<sup>19</sup> A number of substantive options were drafted for consideration. The first reflected the submission of the African Group to BS-WG 2. A second option called for socio-economic imperatives to be considered at all levels in the Protocol and that particular attention be paid to the displacement of particular agricultural resources, cultures, or livelihoods, and to the prevention and mitigation of possible adverse effects. A third option acknowledged the considerable variation in socio-economic considerations among Parties and encouraged further research.<sup>20</sup>

Negotiations on socio-economic considerations from this point forward were very difficult. The debate mainly centered on the need to include socio-economic considerations in the text of the Protocol at all. Many developing countries thought the issue was central to the Protocol, while developed countries found the concept too vague and country specific to have its own provision.<sup>21</sup> The text and options were reduced over the course of BS-WG 4 and BS-WG 5 to one heavily bracketed compromise provision which referred to the prevention and mitigation of socio-economic impacts, the assessment and management of risks with a long observation period, and

encouraging further research on the topic. In addition, it called for Parties exporting LMOs-FFP to notify receiving Parties sufficiently in advance to allow appropriate measures to be taken, providing special assistance in cases involving developing countries.<sup>22</sup> Despite sympathy for the subject, countries could not agree about the need, place and the manner of handling the issue. Because of its bearing on the scope and other provisions for the Protocol, it was necessary for delegations to carefully consider their positions before BS-WG 6.<sup>23</sup>

The Chair's proposed text at BS-WG 6 significantly modified the draft option, providing only that Parties should take into account socio-economic implications of adverse impacts of LMOs, also taking into account human health, especially for indigenous and local communities (ILC) as referred to in Article 8(j) of the CBD. It also encouraged Parties to cooperate on research and information exchange, including early warning to ILC that may be affected economically.<sup>24</sup>

The text was further revised and amended before being transmitted to the First extraordinary meeting of the Conference of the Parties (ExCOP). First, countries added a requirement that import decisions be consistent with international obligations. Second, socio-economic considerations arising from the impact of LMOs was allowed, rather than only those linked to adverse impacts. Third, reference to human health was deleted. Fourth, the value of biological diversity to indigenous and local communities was added rather than a blanket reference to Article 8(j). Fifth, the general reference to research and information exchange on any socio-economic impacts of LMOs, especially on ILC, replaced earlier language on early warning and economic effects to those communities. Sixth, references to socio-economic considerations were removed from Annex II to the Protocol.<sup>25</sup> At the ExCOP, a final addition was made during informal consultations, allowing countries to address socio-economic considerations in domestic measures to implement the Protocol.<sup>26</sup>

As demonstrated by its history, Article 26 was the result of intense negotiation and compromise and is rather limited when compared to some of the legal text initially proposed by developing countries. Like the remainder of the Protocol, it represents a balance between the interests of industrialised and developing countries. Through this compromise, industrialised countries and their biotechnology sectors can be assured that scientific risk assessment remains the primary basis for biosafety decision making, while developing countries are also assured that socio-economic considerations can be relied

upon for some decision-making processes. To bring clarity to the terms of Article 26, the particulars of biosafety decision-making and the relevance of socio-economic considerations are discussed below.

### **Biosafety Regimes and Socio-economic Considerations**

The main basis for biosafety decision making is scientific risk assessment.<sup>27</sup> The focus of scientific risk assessment is on the possible environmental and human health impacts of a new organism or its products, many of which can be measured by traditional scientific techniques. Opinions vary about the value and desirability of including socio-economic considerations in decision-making processes and the introduction of broader socio-economic considerations into biosafety analysis.<sup>28</sup>

Understanding the impacts of modern biotechnology and its products and processes in the context of sustainable development requires looking beyond the physical sciences. New crops and new foods have a trenchant impact on societies across the globe. Their socio-economic effects are as yet undetermined but can be positive, negative, or neutral, and can be expressed by a variety of actors. Some of the concerns are relevant to numerous actors, whereas others are discrete, belonging to a particular group. Some of these concerns are common to both developed and developing countries, whereas others are relevant only to one or the other. Socio-economic impacts are not unique to biotechnology, but taking them into consideration is of particular relevance given the rancorous debate over this technology. The International Law Association's Hague Recommendations on International Law on Biotechnology suggests accommodating a range of legislative responses while also considering different levels of social and economic development.<sup>29</sup>

The limited scope of Article 26 is important to recognise. First, the wording of Article 26(1) limits the use of socio-economic considerations in biosafety decision making to those arising from the impact of LMOs on the conservation and sustainable use of biodiversity.<sup>30</sup> This can be interpreted to mean that where the introduction of LMOs under the Protocol affects biological diversity with potential or actual social and economic repercussions, Parties can justify taking into account such impacts when making decisions on LMO imports or in implementing domestic measures under the Protocol.<sup>31</sup> Second, the provision gives particular recognition to socio-economic considerations arising from the value of biological diversity to indigenous and local communities.

Socio-economic considerations beyond the Cartagena Protocol are those that concern products or activities falling outside the mandate of the Protocol, such as socio-economic considerations related to organisms that do not fall within the definition of LMO, living organism, or modern biotechnology as used in the Protocol; considerations related to LMOs that are not subject to the activities covered by the Protocol (that is, domestic or non-transboundary movement, transit, handling, and use); impacts of LMOs beyond the conservation and sustainable use of biodiversity; and LMOs that are pharmaceuticals for humans and are addressed by other international agreements or organisations. Countries can implement biosafety regulatory regimes that encompass socio-economic concerns beyond those included in the Cartagena Protocol if their regulatory system complies with any other international obligations by which they may be bound. In the context of the AIA and LMOs-FFP procedures for import/export, socio-economic considerations can be used by the importing Party as a basis for decision at that stage.<sup>32</sup>

A literature survey reveals a broad range of sometimes conflicting socio-economic considerations relating to GMOs and LMOs. Careful research to clarify the socio-economic issues related to biotechnology is essential but is not in itself sufficient to incorporate socio-economic considerations into biosafety decisions. Practical steps are necessary for these considerations actually to be taken into account when decisions are made. These steps might include policies that mandate integration of socio-economic considerations into decision-making processes; a clear definition of "socio-economic considerations" and explicit criteria to determine when and where socio-economic assessments are required; identification of the stages at which socio-economic assessments should take place; efficient and cost-effective regulatory processes; and public participation mechanisms to ensure credible assessments and more widely accepted decisions.<sup>33</sup> The following methods have been proposed for taking socio-economic considerations into account: procedures for assessing and addressing socio-economic impacts in risk assessment and management, and subjecting decisions on import of LMOs to prior public consultation processes, especially with respect to communities directly affected by the import decision, for example the local community in which the LMO is destined for field trial or use, or that could be affected by any potential adverse impacts of the LMO on biodiversity.

In 2007, UNEP-GEF received funding from the U.K. Department for

International Development to undertake a scoping exercise on socio-economic considerations in biosafety decision making. The exercise included an information-gathering survey on countries' experience with socio-economic considerations undertaken in cooperation with the SCBD.<sup>34</sup> At UNEP's request, the summary report was circulated as an information note for participants at the fifth Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol (COP-MOP).<sup>35</sup> The responses are instructive of how socio-economic considerations can or should be addressed as a part of the biosafety regulatory regime.

The survey first asked respondents their opinion on the importance of including socio-economic considerations in decision making on LMOs in their country. Eighty-five per cent indicated that socio-economic considerations were either very important or somewhat important, with four-fifths selecting "very."<sup>36</sup> Of the countries having a decision-making system for LMOs in place, two-thirds of respondents stated that it was able to take socio-economic considerations into account.<sup>37</sup>

In those countries where socio-economic considerations were addressed in the decision-making system, most of respondents indicated that the regulatory framework addressed the concept in a general fashion, some indicated that socio-economic considerations were treated on an ad-hoc or case-by-case basis without any explicit inclusion in the decision-making system, and the least number identified socio-economic considerations as being covered through the assessment of particular elements during specific steps in the process.<sup>38</sup> The largest group of responses on how best to incorporate socio-economic considerations into the decision-making process was in favour of a specific, identifiable mechanism; the next largest group supported a general framework for application within the risk assessment process; some respondents supported a participatory process that included a broad spectrum of stakeholders; a few respondents supported an ad-hoc or case-by-case approach; and a small number of respondents were against including socio-economic considerations in biosafety decision making.<sup>39</sup>

The top five socio-economic issues of importance in all countries with a biosafety system were identical: food security, health-related impacts, coexistence of LMOs and non-GM agriculture, impact on market access, and compliance with biosafety measures. More variation occurred with the importance of the next five issues, and depending on ranking, the following



issues arose: conservation and sustainable use of biodiversity; economic impacts of changes in pest prevalence; macroeconomic impacts; farmers' rights; intellectual property rights (IPRs); impacts on consumer choice; economic impacts of changes in the use of pesticides and herbicides; and impacts to indigenous and local communities.<sup>40</sup>

Countries with a biosafety decision-making system had several different ways of considering socio-economic considerations in the decision-making process. An assessment that happens during the risk assessment stage was identified most frequently, followed by an equal proportion of "prior to the risk assessment" and "after the risk assessment." During the appeal, review or renewal of the permit was identified the fewest number of times.<sup>41</sup> Lack of a mechanism for including socio-economic considerations in decision making and lack of capacity were identified as important reasons why assessment was lacking from the decision-making system. Human resources and informational and financial challenges were identified as challenges to the inclusion of socio-economic considerations in decision making. Capacity building and the development of guidelines are thus important mechanisms that could decrease the challenges to and the reasons for not including socio-economic considerations in biosafety decision making.<sup>42</sup> Many countries have adequate capacity to perform socio-economic assessments, but most answered "do not." It is also clear, however, that once decision-making systems are put in place to account for socio-economic considerations, skill levels increase, meaning that increasing the capacity for socio-economic assessment could increase the number of countries that take socio-economic considerations into account in their decision-making processes.<sup>43</sup>

Several conclusions can be drawn from this. First, socio-economic considerations can be taken into account in the decision-making process if countries want to do so. Second, once countries start to incorporate them, they can do this across decisions, across multiple organisms, and across intended uses of the organism.<sup>44</sup> The current practice for including socio-economic considerations in most countries seems to be for one entity to assess socio-economic considerations and a different entity to evaluate the assessment. Three forms of government entity are most often involved in assessment and evaluation: the national competent authority, a multisectoral committee, and/or a government committee consisting of several departments.<sup>45</sup> Although there seems to be a strong consensus that socio-economic considerations should be taken into account, it is less clear how and where socio-economic information should be used. There was the

strongest support for the consideration of socio-economic information at the same time as scientific risk assessment information in the biosafety decision-making process, far less support for considering socio-economic information after scientific risk assessment information, and a split between whether socio-economic information should be evaluated separately from the scientific risk assessment or incorporated into the scientific risk assessment.<sup>46</sup>

A great degree of uncertainty exists over how socio-economic information can be used in biosafety decision making and the weight that it should be assigned.<sup>47</sup> The capacity to undertake and evaluate socio-economic assessments in biosafety decision making varies greatly. Countries that consider socio-economic information in their decision-making systems score high in terms of having people with skills, professional training, or experience to undertake and evaluate that information. Most countries lack adequate capacity to perform socio-economic assessments and might be reluctant to establish a decision-making system depending on socio-economic information.<sup>48</sup>

Countries are in need of capacity building on socio-economic assessment capacity and are seeking a methodologic guide or toolkit on how to undertake socio-economic assessments as a means to start the capacity-building process.<sup>49</sup> Elements that should be considered in biosafety decision making must be identified.<sup>50</sup>

A consensus is forming on the important socio-economic issues and priority areas for capacity building. The socio-economic issues that respondents identified as priorities for capacity building are similar to the socio-economic issues being considered in existing decision-making systems. This will facilitate capacity building and provide guidance on the material to be included in a methodologic toolkit.<sup>51</sup> Further research is needed to show how particular socio-economic considerations can be used to address the priority areas of concern for capacity building and sustainable development.

### **Biosafety, Socioeconomics, and Sustainable Development Law**

The social aspect of sustainable international biodiversity and biosafety law is the least developed aspect in national and international law.<sup>52</sup> This aspect overlaps other areas of sustainable development law, such as the right to food, access to medicines, the right of access to innovations, and corporate social responsibility (CSR). The following section elaborates on

the socio-economic aspect of the Cartagena Protocol in the context of emerging principles of sustainable development law.

### ***Principle of Integration and Inter-relationship***

In accordance with the principle of integration,<sup>53</sup> the Protocol recognises that economic and social development considerations can be pertinent to biosafety decision making in addition to the environmental considerations raised by scientific risk assessments. Specifically, it complies with the emerging customary norm of integration, in that the Cartagena Protocol requires States to “ensure that social and economic development decisions do not disregard environmental considerations, and not undertake environmental protection without taking into account relevant social and economic implications.”<sup>54</sup> Because of its recognition of socio-economic considerations as a fundamental basis for biosafety decision making, the Cartagena Protocol can be categorised as a highly integrative treaty.<sup>55</sup>

The Cartagena Protocol also reflects the interdependence of the needs of current and future generations. The socio-economic impacts of modern biotechnology will be far ranging and affect States from this point on in history. This should be implemented at all levels of governance, because it is essential to the achievement of sustainable development.<sup>56</sup> The principle also calls for States to resolve apparent conflicts between competing imperatives through existing and appropriate new institutions,<sup>57</sup> including the WTO and the Codex Alimentarius, for example. Countries that include socio-economic considerations alongside environmental risk assessments in their biosafety systems also will be creating sustainable development law. Some different ways to include the socio-economic dimensions of biosafety in a domestic regulatory system offer differing degrees of integration.

### ***Principle of Sustainable Use of Natural Resources***

Under the principle of sustainable use of natural resources, States may manage natural resources pursuant to domestic environmental *and* developmental policies.<sup>58</sup> Integrating socio-economic considerations into biosafety decision making plays an important role in determining whether the impacts of biotechnology on biodiversity are sustainable given the potential social and economic costs/benefits. This right is limited by the second component of the principle, the requirement that states must not cause irreparable damage to the territories of other states, or increasingly, the global environment.<sup>59</sup> States are under a related duty to manage natural resources in a rational, sustainable, and safe way to contribute to

the development of their peoples, with particular regard for the rights of indigenous peoples, and to the conservation and sustainable use of natural resources and the protection of the environment, including ecosystems.<sup>60</sup> The specific language of Article 26 of the Cartagena Protocol maps directly onto this duty and is an excellent example of the principle in action. Complicating the principle's application is the requirement that States consider the needs of future generations in determining the rate of use of natural resources, and the related duty of all relevant actors (including States, industrial concerns, and civil society) to avoid wasteful use of natural resources and promote waste minimisation policies.<sup>61</sup> Integrating socioeconomics into the biosafety decision-making process can account for the needs of future generations and help to implement the duty of all relevant actors to avoid waste and promote waste minimisation. Ultimately, the integration of socio-economics is of particular importance because centres of origin and centres of genetic diversity are of crucial importance to humankind, and the conservation and sustainable use of biologic diversity is a common concern of humankind.<sup>62</sup>

### ***Principle of Equity and Elimination of Poverty***

The principle of equity and poverty elimination could significantly inform the use of socio-economic considerations in biosafety decision making. This principle refers to both intergenerational equity (the right of future generations to enjoy a fair level of the common patrimony) and intragenerational equity (the right of all peoples within the current generation to fair access to the current generation's entitlement to the earth's natural resources).<sup>63</sup> The present generation has a right to use and enjoy the earth's resources but is obliged to take into account the long-term impact of their activities and to sustain the resource base and the global environment for the benefit of future generations of humankind. *Benefit* in this context should be understood in its broadest meaning, economic, environmental, social, and intrinsic benefits. Intergenerational equity requires the present generation not to introduce a technology that will irreparably harm the environment or the socio-economic situation left for future generations. This equity also requires, however, that the present generation not deny future generations the possibility of benefiting from biotechnology and its socio-economic gains. Intragenerational equity dictates that biotechnology should be employed to improve the ability of members of the current generation to access resources and reduce poverty and not exacerbate existing inequalities. Biosafety decision making must

incorporate socio-economic aspects for these assessments to be made.<sup>64</sup> The right to development must be implemented to meet developmental and environmental needs of present and future generations sustainably and equitably. This includes cooperating to eradicate poverty, in accordance with Chapter IX on International Economic and Social Co-operation of the Charter of the United Nations and the Rio Declaration on Environment and Development, as well as the duty to cooperate for global sustainable development and attaining equity in growth opportunities for developed and developing countries.<sup>65</sup> All States in a position to do so have a further responsibility, as recognised by the Charter of the United Nations and the Millennium Declaration of the United Nations, to assist States in achieving conditions of socio-economic equity, and to ensure, at minimum, the eradication of poverty.<sup>66</sup>

### ***Principle of Common but Differentiated Responsibilities***

States and other relevant actors have common but differentiated responsibilities and are bound to cooperate in the achievement of global sustainable development and protection of the environment. The principle applies not only to environmental protection but also to development of social goals.<sup>67</sup> International organisations, corporations (including in particular transnational corporations), NGOs, and the rest of civil society should cooperate with and contribute to this global partnership. Corporations have also responsibilities pursuant to the polluter-pays principle.<sup>68</sup>

Differentiation of responsibilities, although based mostly on the contribution that a State has made to the emergence of environmental problems, must also consider the economic and developmental situation of the State.<sup>69</sup> Notably, the special needs and interests of developing countries and of countries with economies in transition, with particular regard to least developed countries (LDCs) and those affected adversely by environmental, social, and developmental considerations, should be recognised.<sup>70</sup> From a sustainable development law perspective, biosafety decision making that permits socio-economic considerations may allow States to meet their common responsibility to ensure that there is adequate protection for the safe transfer, handling, and use of LMOs while providing a method for their economic and developmental situation. Ultimately, the principle suggests that the concept of common but differentiated responsibilities can be used to interpret and strengthen other corresponding principles of sustainable development law in situations of overlap or conflict between social, economic, and environmental regimes.<sup>71</sup>

### ***The Precautionary Approach to Human Health, Natural Resources, and Ecosystems***

Article 26 allows Parties to consider socio-economic considerations when deciding on importing an LMO when the impact of the LMO on the conservation and sustainable use of biodiversity is concerned. In turn, both the AIA and LMO-FFP decision-making procedures allow precautionary decision making in light of insufficient scientific evidence on the extent of the potential adverse effects of an LMO on the conservation and sustainable use of biodiversity. Given the uncertainty over the socio-economic impacts of LMOs and how these could affect biodiversity, the ambit of the allowable precautionary decision-making in Articles 10(6) and 11(8) seems that it include socio-economic factors, at least to the extent that these can be considered “relevant scientific information and knowledge.” Of course, States are also free to include socio-economic considerations in determining whether to make a precautionary decision under their own decision-making processes outside the Protocol as long as this does not conflict with their other international obligations.

### ***Public Participation and Access to Information and Justice***

There are three dimensions to this principle. First, individual people should have the opportunity to participate in official decision-making processes and activities that affect and impact their lives and well-being directly.<sup>72</sup> Second, to participate effectively, the public must have access to adequate information concerning the issues, decision making, and policy making in which they are able to participate.<sup>73</sup>

Finally, when people’s rights have been infringed or when they have suffered harm, they should have access to administrative or judicial processes to challenge the measure and claim compensation.<sup>74</sup>

Numerous aspects of socio-economic considerations in biosafety decision making relate to these three dimensions. The first dimension suggests that public participation should be a common component in all biosafety regulatory regimes, because these regimes relate to socio-economic development. In other words, because biosafety decision making can directly affect people’s lives and their well-being, these same people should have an opportunity to participate in the decision-making process. Indeed, the Protocol requires public consultation in decision making as well as public participation on the safe transfer, handling, and use of LMOs in relation to the conservation and sustainable use of biologic diversity, also

considering risks to human health. These are quite broad requirements that can be fulfilled in several ways.

The second dimension on public access to information is also reflected in Article 23 of the Protocol. This article requires that parties “[e]ndeavour to ensure that public awareness and education encompasses access to information on living modified organisms identified in accordance with the Protocol that may be imported.” Much of the literature also recognises that consumers want labelling of genetically modified foods or at least want to be able to find out what is in the food they consume. Consumers’ reasons for wanting to know may well be based on socio-economic factors (for example, not wanting to consume something they feel runs counter to their philosophical values) rather than on environmental or health concerns. Biosafety regulatory regimes that are intended to support sustainable development need to consider how to fulfil the requirement of public access to information.

The final dimension is access to justice for people who think that their rights have been violated. Access to justice is necessary in cases of biosafety wrongdoing that harms socio-economic rights. This could include the ability to be compensated for damages when there has been a socio-economic biosafety injury (for example, lost profits by organic farmers whose crops no longer command a premium because they contain introduced DNA).

### ***Principle of Good Governance***

The importance of the principle of good governance in the inclusion of socio-economic considerations in biosafety decision making hinges primarily on its relationship with other principles of sustainable development law. The characteristics of good governance reinforce these other principles. Biosafety regulatory regimes that incorporate these principles result in systems that respond to the concerns of individual people and help to build consensus by acknowledging and not excluding the socio-economic elements of biotechnology and biosafety. In turn, this encourages participation in the biosafety process rather than creating disillusionment and disenfranchisement. Ultimately, it can lead to national visions of biosafety that incorporate and reflect the ideas of all. Perhaps most important, building biosafety regulatory regimes around these principles of good governance helps to create regimes that integrate the other principles of international sustainable development law.

## Conclusion

To varying degrees, many countries already consider socio-economic factors within their biosafety regimes and recognise that socio-economic considerations can be an important part of biosafety decision making. Although socio-economic assessment of new and emerging technologies, including LMOs, is an invaluable tool supporting decision making, it can present a difficult hurdle if the assessment procedure is not clearly defined.<sup>75</sup> The main concern is to determine at which stage of the regulatory process inclusion is most useful, while maximising the functionality of the biosafety system.<sup>76</sup> The lack of a clear mechanism for the incorporation of socio-economic information into the process and the limited institutional capacity for socio-economic analysis in many countries are key barriers to the broader use of socio-economic considerations in biosafety decision making.

Socio-economic considerations in biosafety target values that states have already acknowledged as relevant and important. Numerous human rights treaties proclaim the rights of individual people to adequate food, work, and health. Nascent human rights to the environment are also emerging. These are just a few of the rights that could be affected by the socio-economic impacts of the products and processes of biotechnology. States that are party to the different treaties in which these rights are enunciated are bound to uphold these rights. In the realm of trade, members of the WTO are bound by the terms of the Sanitary and Phytosanitary Agreement (SPS) Agreement, which lists relevant economic factors that members must consider in their risk assessments and determination of the appropriate level for sanitary or phytosanitary measures. These include the potential damage in terms of loss of production or sales, the costs of control or eradication, and the relative cost-effectiveness of alternative approaches.<sup>77</sup>

Given that the socio-economic capacities, priorities, and processes of one region or area might not be identical to those of other regions, further analysis of biosafety decision making in different parts of the world is needed.<sup>78</sup> The elements of socio-economic considerations relevant to biosafety decision making remain to be clearly defined, and an expert committee might be necessary to identify appropriate methods. Case studies and examples of different methods for assessing socio-economic issues and their strengths and weaknesses should also be undertaken to guide practitioners.<sup>79</sup> The development of an institutional framework for the incorporation of socio-economic considerations in biosafety decision



making needs to be undertaken by first determining which institutions are most competent to address the issues. Methods should be identified and developed for use in the decision-making process, as well as methods for how to obtain stakeholder input during that process. Examples of decision-making frameworks and institutions that have been successful in incorporating socio-economic considerations also should be identified and described.<sup>80</sup>

From a sustainable development law perspective, the consideration of socio-economic information as a part of the biosafety decision-making process brings the field of biosafety closer to the goal of sustainable development through the integrated consideration of economic and social development, and environmental protection. Obtaining information and knowledge on socio-economic issues further supports biosafety regulatory regimes that can contribute to sustainable development and demonstrate how to build synergies between economic, environmental, and social law.

## Endnotes

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# Governance of Biotechnology in Africa: The Challenge of Reconciling Interdependencies and Differences

Julius Mugwagwa\* and Diran Makinde\*\*

**Abstract:** The article argues that an informed understanding of the differences and interdependencies among different stakeholders within the biotechnology and biosafety arena is a key issue in the unpacking of challenges facing development and implementation of biosafety systems in Africa. Advocating for a move beyond rhetoric, the article calls for a more nuanced and context-driven approach to biosafety as an avenue for raising chances of success for policy processes and making best use of available resources. Failure to adequately define and delimit the interests and concerns of various stakeholders, and embedding them within a science-based assessment of biosafety brings more harm than good to efforts by countries to develop and implement biosafety systems.

**Key words:** Biosafety, Africa, risk assessment, policy making.

## Introduction

The process of developing and implementing biosafety systems across Africa is not a straightforward exercise. This reality is acknowledged by stakeholders on the continent, and those outside who are making efforts to assist African countries achieve this objective. Finding of the best way to untangle the complexities and forces around the desired policy outcomes faces many realities, some of which have both positive and negative impacts on the processes depending on how they are framed or managed by contending actors. This article reflects on policy-making processes in agricultural biotechnology in Africa especially, Sub-Saharan Africa (SSA), examining how interdependencies and differences of interests and

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aspirations among stakeholders at cross-national, national and institutional levels coalesce to inform, facilitate or constrain policy processes. This article is based on observations and reflections of the NEPAD Agency African Biosafety Network of Expertise (ABNE) which was established in 2008 to build functional biosafety systems in Africa. The aim of this article is to explore and discuss the relationships that emerge between regulators, public and private developers of the technology, intermediaries, as well as the lay public and how these may best be managed for the benefit of the policy processes.

Participation of multiple stakeholders in decision making processes is important, yet in most cases a lot still needs to be done beyond participation, to ensure that the representation of stakeholder concerns also influences the outcome of decision making processes, and importantly helps in alleviating the socio-economic challenges that the continent faces perennially. The ABNE was established to provide a broad-based platform for context-driven formulation and implementation of biosafety systems across Africa.

### **Biotechnology**

Biotechnology is a pervasive technology, which brings together interests from many sectors including research and development, product development, manufacturing, commercialisation and downstream delivery. Management of this technology at the policy and regulatory levels is, therefore, inherently multi-level and multi-actor, and this brings both challenges and opportunities for policy actors. In the Sub-Saharan Africa region, there have been many efforts since the early 2000s towards developing and implementing systems for managing biotechnology. There are many individual, institutional, sectoral, national, regional and international players in these efforts and their multiplicity and varying levels of involvement in the issue in space and time brings many dynamics to these efforts for developing countries.

### **Role of technology**

It is recognised that new technologies can play an important role in addressing food security challenges the world over, including Sub-Saharan Africa (FAO 2004). However, efforts to effectively access and exploit technological knowledge are at the mercy of various context specific economic, political, social and cultural realities. In SSA countries, where the vast majority of the population relies on farming for their livelihood,

it is important to consider the impact of policy making processes on food security and the socio-economic status of poor farmers (Mugwagwa *et al.* 2010).

The mechanisms that are developed for technology governance reflect a myriad of complex realities. Regulations as instruments of technology governance provide the norms and standards for quality, safety, effectiveness, environmental protection, intellectual property protection, among others. With regard to modern biotechnology in agriculture, developing countries recognise the importance of effective regulatory systems (Persley 1999). The ways in which biotechnology is governed not only determine its ability to achieve socially desired aims, but also give important signals about the direction of technology development (Cohen and Paarlberg 2004). The two elements are linked insofar as the credibility and legitimacy of new technologies, which to some extent may be strengthened by incorporating public consensus in policy processes, are important in facilitating technology use and development (Jaffe 2004).

In Sub-Saharan Africa, like elsewhere in the developing world, the quest for new technologies and new ways of working together across disciplines, sectors, countries and regions is now widely seen not as an option but an imperative in the pursuit of socio-economic stability. There is a new and rising reality that new and old problems alike have become increasingly pervasive, defying disciplinary, sectoral, national or regional boundaries. Within these arenas exist opportunities and solutions to the problems, and as well avenues for magnification of the problems (Mugwagwa 2010). Challenges have increasingly become unusual in their magnitude, in the way they spread and in the way they combine with others to present even bigger challenges. Innovation is seen as a way of breaking new ground, breaking barriers and doing business away from the beaten path, and ensuring that effective technologies, products and services do indeed reach the millions of people who need them. With respect to addressing food security challenges, the role that new technologies can play are widely recognised the world over, including Sub-Saharan Africa (SSA) (FAO 2004; UNCTAD, 2010). It is also widely acknowledged that a nation's ability to create, acquire, accumulate, diffuse and utilise scientific and technological know-how and knowledge is a major determinant of its capacity for the industrial and socio-economic development needed to improve people's livelihoods. Differences in the acquisition, accumulation, diffusion and utilisation of science, technology and innovation go a long way in



explaining the income disparities between rich and poor countries (Juma and Serageldin 2007). Admittedly, efforts to effectively access and exploit technological knowledge face various context specific economic, political, social and cultural realities.

In SSA, a myriad of efforts have been made at various levels to harness and deploy technologies to reign in food insecurity and other socio-economic challenges bedevilling most of Africa. For example, biotechnology, viewed as a continuum of both traditional and modern biological techniques, is one of the technologies which has been at the centre of many efforts and is largely seen to (yet) have a significant role to play in mitigating some of the challenges and leapfrogging Africa to higher levels of development and self-sufficiency. A number of challenges confront these efforts, among them being the lack of effective innovation systems (UNCTAD 2010). Focusing specifically on how to reverse declining agricultural productivity, UNCTAD, the Consolidated African Agricultural Development Plan (CAADP) and a number of other organisations and frameworks all point to the need for creation and employment of 'agricultural innovation systems', which would provide an 'enabling framework' not only for adoption of existing technologies, but also the development of new ones suited for African needs.

### **What is an Enabling Framework and What Does It Do?**

Creating an enabling environment is a critical step in the quest to harness and deploy technologies (Chataway *et al.* 2006; Juma and Serageldin 2007). In Technology and Innovation Report 2010, UNCTAD defines an enabling environment for technology and innovation in agriculture as 'one that provides the actors, skills, institutions and organisations required to promote the use, dissemination, diffusion and creation of knowledge into useful processes, products and services' (UNCTAD 2010: xiii). The ability of the agricultural innovation system to be able to access, use and diffuse knowledge embedded in agricultural technologies depends on the presence of an enabling framework that supports the emergence of technological capabilities by strengthening existing linkages, promoting new linkages and fostering inter-organisational learning that leads to capital accumulation and technical change. Such an enabling environment, by definition, is one that strengthens the absorptive capacity of local actors while protecting their interests through a policy framework that recognises their legal rights and privileges, linkages, socio-cultural norms and historical context (UNCTAD 2010: xiii).

Among many motivations, this article stems from a desire to contribute to understandings of the context-specific differences and similarities embedded in or transcending processes to establish and employ biosafety systems as an enabling tool for harnessing the benefits of modern biotechnology while minimising the risks posed by the same. This technology is seen as one key ingredient in the toolkit of solutions for addressing food insecurity and broader livelihood challenges in developing countries.

### **Knowledge and Power Key in Policy Processes**

One of our key observations at ABNE is that knowledge and power are central elements in policymaking processes in Africa. Biotechnology is knowledge intensive and problems around it, including social ones, are generally couched in scientific terms. Nevertheless, scientific considerations and political power are intertwined in decision making processes. Shore and Wright (1995) highlight, *"Policies are most obviously political phenomena... 'political technologies advance by taking what is essentially a political problem, removing it from the realm of political discourse, and recasting it in the neutral language of science'.*<sup>1</sup> *Central to this process is the use of 'expert' knowledge in the design of institutional procedures."* The relationships that are dominant in framing regulations are based on a dynamic and complex interplay between knowledge and power.

Scientific evidence plays a dominant role in the decision making process of biotechnology. However, contrary to some assertions, 'experts in science' do not necessarily override in all instances of policymaking. The uncertainty surrounding biotechnology provides a possibility to supersede 'scientific evidence' and apply the precautionary principle. *"The precautionary principle is not a natural scientific concept but a policy principle which is meant to illuminate the credibility of the idea of anticipatory policy and to create new coalitions. In that context the precautionary principle holds that policymakers will sometimes have to decide on action even if there is no scientific evidence of a causal link"* (Hajer 1995:67). This leaves open the possibility that if science is not leading to a decision that is favourable to the national socio-economic good, decision-makers can disregard it on the basis of the uncertainty on potential risks and evoke the precautionary principle.<sup>2</sup>

The processes through which regulatory systems emerge are driven by complex forms of interactions amongst actors. To a large extent, the interactions are underpinned by the nature of knowledge for which the regulatory mechanisms are developed as well as the power dispersal, which

influences the orientation of the regulations (Francis 1993). The knowledge intensive nature of biotechnology and the high uncertainty surrounding possible human and environmental risks tends to overwhelmingly favour scientific and technical (such as legal professions') expertise in decision making processes. Other actors that may have a relatively strong influence in shaping biotechnology regulations are private investors, although, their influence closely depends on the government's position with regard to its strategic economic priorities.

### **Long Tradition of Mediating Multiple Stakeholder Interests**

The establishment and implementation of the ABNE follows an age-old African tradition of creating and implementing framework for coordinating scientific efforts. Documents efforts emerged as far back as the late 1920s and led to the African Survey in 1936 (Gruhn 1971). The organisations that emerged out of these efforts primarily aimed at establishing a common communications network that could enhance utilisation of African resources.<sup>3</sup> What has also emerged over the years and as observed in the biotechnology and biosafety terrain is a shift from top down, exclusive approaches - which have received incessant criticism in recent times to a bottom-up approaches. However, the bottom-up approach may not be clearly evident in all biotechnology decision making processes in SSA, with some organisations being labelled as techno-savvy 'champions' of the technology. Invariably these 'champions' are a direct product of the pre-existing structure (top down model); they generally have a history within public research institutes, but have been 'entrusted' with representing the concerns of the poor in biotechnology decision making process, not in the least because of their apparent advisory independence. They are thought to have strong links with the poor and, therefore, well imbued with their concerns and at the same time to be in a strong position for independently articulating the socio-ethical concerns in the highly scientific problem framing contexts of biotechnology policy.

The 'champions' operate within networks and are seen to play an important role of mobilising and engaging a wide range of actors whose views are then represented in policymaking processes. While the extent to which such activities revolve around knowledge exchange rather than on persuasion is a matter of debate, our perceptions is that various forms of cumulative and path dependent learning are occurring within this linear model, on account of its ability to recreate itself, and capacity to persist. Importantly, it is crucial within these interactions, meaningful reflexivity

with some potential for institutional change to reflect the needs of poor consumers and farmers should take place. The diversity of sites and the types of knowledge that contribute to decision making processes ought to be expanded and sustained. The ABNE has implemented a number of activities to this end in collaboration with other partners in the biosafety arena.

### **Recognition of Core Competencies is Key**

Agricultural biotechnology is a knowledge intensive form of modern technology. It requires a strong scientific knowledge base of core competencies. This can facilitate adequate assessment of potential risks and benefits as well as provide sufficient flexibility for incorporating the emerging scientific evidence and shifting boundaries of social and ethical debates that raise fresh challenges to the credibility of biotechnology. Our experience at the ABNE confirms that suitable scientific and technical competences in risk assessment are limited in many SSA countries. This is further compounded by the fact that other forms of competencies for articulating socio-ethical concerns also tend to be scarce in SSA. For example, competencies for information communication and management, which are critical in developing an official and effective information strategy aimed at providing actors with sufficient transparency to allow for better articulation of specific interests, are limited in most countries, necessitating the need for partnerships and synergies among different interest group. An adequate information strategy has multiple roles including not only for educating the public and countering 'extremist' views, but also for gauging public attitudes, which are important in guiding institutional changes that are necessary in facilitating biotechnology innovation strategies as well as policy development and implementation (Levidow 2007).

There are constant fears that the scenario in SSA could imply that those with scientific and technical competencies (though limited) drive decision making processes based on the deficit model of knowledge production (Kingiri 2010). SSA countries for the most part rely on bilateral and international assistance as well as multinational companies to develop scientific and technical competencies and formulate regulatory frameworks (Cohen and Paarlberg 2004). As such it is not sufficient to only recognise that biotechnology is important in the development process in Africa. The challenge lies in identifying and implementing interventions that adequately take technological capability building into account (important within the context of early development stages of SSA economies), and provide robust solutions to the pressing social challenges. Related to this

is the importance of understanding that the existing perceptions on the role of scientific capabilities do indeed have potential to shape the existing decision making processes in agricultural biotechnology. The NEPAD Agency's co-evolution approach operationalised through the African Biosciences Initiative (ABI) and the ABNE aims to address both the scientific capacity challenges and perceptions on regulatory trajectories (Juma and Serageldin 2007)

Scoones (2002b:116) notes that a key assumption of pro-poor agricultural biotechnology advocates is that "regulatory issues will be dealt with throughout the world by international 'capacity building' efforts in developing standardised, harmonised regulations for the agricultural biotechnology sector. With new regulations in place these will be enforced consistently and effectively throughout the developing world." Such efforts of capacity building and harmonisation of regulation may provide simple and standardised regulatory procedures that encourage investment in the biotechnology industry may facilitate trade, but may not substantially promote the achievement of context specific moral imperatives. There are numerous aspects that limit the ability to effectively incorporate the concerns of the poor in biotechnology regulatory frameworks (Newell 2002; Glover 2003).

The 'science-based approach' to problem framing is intricately and determinately tied to the knowledge intensive nature of biotechnology and appears to be core in determining the extent to which a range of objectives are achieved. Attempts to incorporate the concerns of poor farmers and consumers in SSA are generally undertaken by 'champions' who mainly operate within non-governmental organisations (NGOs). NGOs are, therefore, thought to have strong links with the poor and are at the same time in a better position to articulate their socio-ethical concerns in the highly scientific problem framing contexts of biotechnology regulation. Rayner (2003:165) points out that: "NGOs tend to explain their motives for supporting public participation in terms of extending democratic control". However, in SSA 'champions' (or the NGOs within which the 'champions' operate) who wield the strongest influence on decision making processes cannot be assumed to hold interests that are entirely compatible with extending democratic control to the public (Harsh, 2009:231). The formulation of a regulatory framework is further complicated by the continuously changing regulatory environment and, therefore, offers no standard approach of reflecting the heterogeneity of the complex contextual

realities. This raises critical questions in terms of incorporating context specific realities of SSA such as the challenge of food insecurity and the socio-economic status of poor farmers.

While it is obvious that issues of safety and environment dominate the ways in which the biotechnology innovation trajectory is evolving in SSA,<sup>4</sup> it is difficult to argue that these aspects dominate the public debates that relate to policy making processes at the local level. Contestations of biotechnology are closely tied to the apprehension that stems from the power imbalance in externally triggered processes.

There are clear though perhaps not sufficient attempts to define risk more broadly and include the relationship between biotechnology innovation and food security. Nevertheless, this does not interrogate the ability of 'sound science' to tackle the broader socio-economic challenges of the poor. Furthermore, 'sound science' is in some cases viewed as a magnet for pursuing the harmonisation of regulatory systems in the region. Numerous discussions about the importance of pooling resources in the region encourage countries without sufficient scientific and technical capabilities as well as funds to engage in harmonisation processes because missing such opportunities is viewed as a risk in its own right (Mugwagwa 2010). It is also not uncommon for SSA countries to borrow key elements of bio-policy from the few that already have one without necessarily questioning core defining elements of innovation trajectories. Wafula and Clark (2005) report that: "Uganda was open in terms of borrowing key elements and tenets of a biotechnology policy from countries such as Kenya, Zimbabwe, South Africa, Namibia and the European Union."

The biotechnology discourse is enshrined in 'champions' whose framings of the connection between biotechnology innovation and food insecurity are shaped by perspectives that are contradictory and fragmented. Zambia is perhaps an exception as was demonstrated by the 2002-2003 food crisis. It is noted that the decision making process on whether to accept GM food prominently featured the Zambian scientific community that was able to focus *'not only on purely scientific evidence, but also on the potential political and economic impacts of allowing GM food aid into the country'*, (Clark *et al.* 2007).<sup>5</sup> Nevertheless, Glover (2003) notes that: "In countries which lack the capacity to compete in biotechnology, or where the degree of vested interests or the intensity of controversy is low, it is more likely that participation will be feasible and that public concerns will be allowed to frame the issues under consideration, as well as shape the decisions to be

made.” On the whole, however, narrow perspectives of biotechnology in most SSA continue to have a disproportionate role in influencing policy. ‘Sound science’ determinately guides the formulation of biotechnology regulation and innovation in SSA. While this is not a peculiarity of SSA countries, the emergence of ‘champions’ influences the relationships in decision making processes in specific ways. For example, the existence of ‘champions’ takes the public one step away from questioning the extent to which science on its own can adequately take into account the challenge of food insecurity and the socio-economic status of poor farmers.

It would be disingenuous to suggest that the ‘divinity’ attached to science is unshakable in SSA, particularly owing to the rapid changes that are occurring in the wider spectrum, for example, with regard to information and communication technologies. Nevertheless, public participation remains encapsulated in ‘champions’ and is largely about persuasion rather than consultation, (Harsh 2009). The adherence of ‘champions’ to a knowledge (biotechnology) elite community gives them considerable influence in decision making processes, particularly owing to the uncertainty that surrounds biotechnology (Keeley and Scoones 2003). It is difficult to argue that in SSA the biotechnology debate in decision making processes is evolving towards the more mature debates in the north. That notwithstanding, decision making processes are intrinsically ‘evolutionary’, and the existence or absence of opportunities for effective public participation in one period does not preclude variations in the future.

### ***Implications for Food Insecurity and the Concerns of Poor Farmers***

The inclusion of public participation in biotechnology decision making processes is important and will continue to be seen as necessary, although it is difficult to argue that it has had a positive and significant impact in aligning biotechnology innovation to social needs in SSA. In some countries, decisions about biotechnology innovation trajectories have largely been driven by external efforts such as international research institutes, donors and non-governmental organisations and public participation has been facilitated informally through public-private partnerships. The role of the government has been in some cases mainly reactive and its ability to guide biotechnology innovation, let alone align it to local needs, has been minimal (Harsh 2005). It is, nevertheless, important to emphasise that public participation is not the panacea for addressing the needs and ecological environments of poor farmers and consumers.

The ability to adequately factor practical problem-solving mechanisms for socio-economic issues into innovation processes requires a systems approach to innovation (Hall 2005). Even within such a holistic approach public participation though important cannot serve as a 'silver bullet' to agricultural constraints. One of the shortcomings of the systems approach in its application to SSA relates to the central question of demand and innovation. Whilst demand dynamics are viewed as critical in stimulating and defining technology paths that are congruent to the consumer and may perhaps better reflect the preferences and concerns of the public, SSA does not provide a very strong case in support of this argument in agricultural biotechnology. As mentioned previously, intermediary consumers of biotechnology, particularly private investors in the biotechnology industry (that for the most part target secondary markets) play a critical role in stimulating demand and orienting the innovation trajectory.

In the case of industrialised countries it may be argued that: "[O]ur consumption decisions are likely to have a greater impact in shaping our lives than our ballots. Thus, popular choices about governance seem to be increasingly made in the marketplace rather than in the legislature", (Rayner 2003). Neither ballots nor consumption decisions in SSA seem to offer much in terms of shaping governance. However, a systemic approach provides a premise for addressing the shortcoming of agriculture in a more integrated way by identifying gaps and providing solutions from a holistic perspective. Other strands of literature such as the value chain analysis also provide avenues to identify broader and complementary channels for responding to the concerns of poor farmers and consumers in SSA (Kaplinksky 2005).

## Conclusion

This article has sought to illuminate the nature of relationships that exist in policy processes in SSA. It demonstrated that effective public participation or more specifically the adequate representation of the socio-economic realities facing poor farmers and consumers in biotechnology decision making processes, despite its importance, is often not given consistent and effective attention. However, the existence or absence of opportunities for effective public participation in one period does not preclude variations in the future. Decision making is a continuous process, which involves iterating negotiations that evolve with changing needs in a path dependent way and are principally based on continuous learning. Nonetheless, while it is not expected that improved representation would on its own be sufficient in addressing the challenge of food insecurity and the plight of



poor farmers in SSA, it can make an important contribution to attempts for aligning biotechnology to the socio-economic welfare of the poor. Equally important is the importance of managing differences and dependencies amongst different actors within the arena.

## Endnotes

- <sup>1</sup> Quoted from *Dreyfus and Rabinow (1982:196)* by Shore and Wright (1997)
- <sup>2</sup> See the case of Zambia's refusal to accept milled GM maize during the 2002-2003 food crisis. (Clark *et al.* 2007)
- <sup>3</sup> These efforts led to the creation of the Scientific Council for Africa South of the Sahara (CSA) in 1949, and the Commission for Technical Co-operation in Africa and Scientific Council for Africa South of the Sahara (CCTA) in 1950.
- <sup>4</sup> For example, in Ethiopia which has wide ecological diversity and rich biological resources, the leading authority in the formulation of a biosafety policy is reported to have adopted precautionary principles that limit the use and development of biotechnology; it weakens the purported argument of focusing on small farmers and seems strongly guided by concerns of biopiracy (Ayele 2007). In a different scenario, it has been suggested that SSA serves as a battle ground for EU-US disagreements on GM trade. The US aggressive approach confronts the EU cautious approach to GM crops by expanding biotechnologies in SSA - a source of EU agricultural products - and in so doing seeks to encourage the EU to develop more accommodating biotechnology policies (Clark *et al.* 2007:101). The financial resources accruing to SSA from such disagreements cannot be overlooked as an important element drives local debates.
- <sup>5</sup> This may have been and perhaps paradoxically facilitated by the absence of a vibrant biotechnology industry.

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# Socio-economic Considerations and LMOs: The Case for an Appropriate and Integrated Framework

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**Abstract:** Although Article 26 of the Cartagena Protocol enables countries to take into account socio-economic aspects in decision-making with respect to Living Modified Organisms (LMOs), translating that into practice has not been easy. Countries have followed different approaches; while some countries have chosen to use a comprehensive list of socio-economic impacts they want to assess, some countries have not given to this much importance. This article explains the need for taking socio-economic aspects into account and analyses the practices followed in this. It suggests a model that differentiates technology regulation from decision-making taking into account the socio-economic aspects. This model takes into account the socio-economic aspects in four stages of commercialisation and it is suggested as a suitable model for developing countries.

**Key words:** biosafety, commercialisation, LMO, Cartagena Protocol, technology assessment

## Understanding the Need for Socio-economic Considerations

In the negotiations for United Nations Protocol on Biosafety, a coalition of representatives of the Third World countries, civil society organisations, etc., advocated for strongly worded socio-economic regulation of biotechnology. After protracted negotiating this resulted in the Article 26 of the Cartagena Protocol on Biosafety (CPB), which deals with Socio-economic considerations (Kinchy *et al.* 2008). At the global level, as there is no other convention to deal with Socio-economic Considerations (SECs) in biotechnology regulation, the CPB has emerged as the central convention that permits taking into account both biosafety considerations and SECs arising from the impact of LMOs on the conservation and sustainable use of biological diversity. CPB being a Convention negotiated under

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Convention on Biological Diversity (CBD) the emphasis on conservation and use of biodiversity is understandable.

Though the CPB came into force in 2003, socio-economic aspects have not been given much importance in terms of implementing Article 26 in letter and spirit. Only 56 per cent of the National Biosafety Frameworks mentions SECs.<sup>1</sup> However, the mere mention of SECs does not guarantee that they have been fully incorporated in the framework. Often regulations of different countries reveal lack of clarity on SECs, while methodological issues create a problem in implementation since there is no clarity on that (Chaturvedi *et al.* 2012).

Moreover, socio-economic impacts of GMO market approvals are considered in a broad range of countries including Armenia, Bangladesh, Bhutan, Cambodia, China, Honduras, India, Lebanon, Mauritius, Nigeria, the Philippines, South Korea, and the Syrian Arab Republic. However, the scope and nature of requirements seem to vary considerably between these countries as does the way they are being established in the part of national legislation, draft legislation, policies or regulatory practice. On the other hand the USA, Canada, Japan, and Thailand are examples of countries which have not taken into account SECs. Among the EU/EEA Member States, only France and Norway are known to explicitly assess socio-economic impacts; the Austrian national law on GMOs includes a provision on socioeconomics which has not yet been implemented though (Spok 2010). Although socio-economic considerations are included in the biosafety frameworks of a number of countries worldwide, regulatory experience seems to be limited (Zepeda 2009; Anita *et al.* 2011). Although Article 26 is concerned with SECs the need for including SECs in decision making has to be understood in a broader context. Article 26 thus can be a guiding article and Parties are at liberty to go beyond the requirements under Article 26 in taking SECs into account in decision-making.

Socio-economic considerations is a broad term although the focus of its usage in Article 26 is specific. Taking into account Socio-economic Impacts and Environmental Impacts of technologies is part of policy making and Technology Assessment exercises take into account broader implications and impacts of a given technology. Similarly, methods like Constructive Technology Assessment (CTA) try to integrate the expectations from the technology into technology assessment so that the scope for directing technological change is explored. Similarly, the Environmental Impact Assessment has been part of decision making and it is mandatory under

various laws to protect the environment and to control pollution. In case of agricultural technologies there is enough literature on impacts of Green Revolution on employment, on different classes of farmers, on women and in general on the socio-economic impacts of Green Revolution. But most of these studies have been done after introduction of Green Revolution and these studies have helped in assessing the impacts of Green Revolution and to take suitable steps to minimise the negative impacts of Green Revolution. For example, studies indicated that the introduction of mechanised farming during the Green Revolution increased the inequity between small-scale and large-scale farm communities (Conway 2003) and reduced the availability of agricultural jobs performed by women (Paris 1998).

In recent years, the idea of Anticipatory Governance of technology has been put forth as another mechanism and this goes beyond Technology Assessment as the idea is that governance of technologies is needed at different levels. Governance is a broader term than regulation and part of the Governance process includes dynamic assessment of impacts of technology and anticipating the potential impacts taking into account the trends and trajectories in technology. In case of nanotechnology and synthetic biology and technological convergence, these new ideas are being debated while CTA is being practiced in Europe.

Technologies never operate outside a biophysical and social context, and it is their interaction with their contexts that generates effects, impacts and implications. In order to identify and evaluate the potential harms and benefits of a technology, we must know how it is likely to interact with its context, which requires knowledge of specific contexts as much as it requires knowledge of the technology itself. However, in case of technologies that have a wider and long-term impact assessing their impacts is not easy because it is difficult to assess accurately all the impacts of a technology. Moreover, the diffusion and use of technology is also affected by the impacts of the technology resulting in unanticipated developments and impacts. In case of LMOs, their impacts need not be confined to agriculture and food production and environment (Pavone *et al.* 2011). The Agenda 21 recognising this suggests:

*“Like with most new technologies, research in biotechnology and the application of its findings could have significant positive and negative socio-economic as well as cultural impacts. These impacts should be carefully identified in the earliest phases of the development of biotechnology in order to enable appropriate management of the consequences of transferring biotechnology.”<sup>2</sup>*

Nationally and internationally risk perceptions about LMOs (i.e. GMOs) have a role in public's acceptance or rejection of GMOs, particularly in agriculture and food. It is obvious that understanding public perceptions of risk related to LMOs depend critically on understanding the socio-cultural factors involved (Finucane 2002). For LMOs in agriculture and genetic engineering an important question is whether genetic engineering is compatible with nature, that is, are they safe enough to be used without damaging nature (Ramjoue 2008). Here also perceptions of risk matter and risk assessment is done to assess the consequences of introducing LMOs in natural environment including the long-term impacts on biodiversity.

### Issues in Defining SEC

There is no clear definition as to which aspects can clearly be defined as falling within the scope of SECs. Basically every possible effect that does not clearly constitute a direct environmental or health effect could be considered as SEC (for example, any direct or indirect effect linked to LMOs becoming manifest in society). Consequently, the meaning and use of the term varies in the literature. Often the focus is on economic and/or social factors, but sometimes ethical issues are also included (Norwegian Gene technology Act 1993). While in India its biosafety system provides for evaluation of the economic benefits of LMOs through systematic evaluation of agronomic performance; under the Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts 1998, it has been specified that data should also be generated on economic advantage of the transgenic over the existing varieties. Though there is an environmental objective, most of the provisions have a direct bearing on agricultural production practices as also on the trade and commerce. India is now developing a comprehensive regulatory framework by establishing Biotechnology Regulatory Authority of India (BRAI) to regulate biotechnology (Chaturvedi *et al.* 2012).

Further, while discussing the scope of SECs it also needs to be considered that when a country includes SECs in the LMOs biosafety regulatory process it has to decide if the SECs should be voluntary or mandatory or if it should be carried out for approval (*ex ante*) and/or for post-release monitoring (*ex post*) and which methodology should be applied. For *ex ante* studies the choice of methods is limited and they necessarily will be based on projections and assumptions.

Comparison of current approaches to the inclusion of SECs in the GMO regulatory process in Argentina, Brazil and China shows significant differences. In Argentina, SECs are mandatory and comprise the *ex ante* assessment of economic impacts on trade and competitiveness. Brazil has introduced a non-mandatory SECs with an open scope and it is decided on a case-by-case basis if they are used. In China, the SECs are currently not included in the guidelines and regulations (Lusser *et al.* 2012).

Moreover since the overall scope for socio-economic assessment seems to be extremely broad, the question of the boundaries of a socio-economic assessment is highly pertinent. Baselines are needed to be defined for socio-economic assessment. It needs to be discussed which socio-economic impacts are considered acceptable, desirable or avoidable. It has been felt as a need that a definition of terms and indicators is needed and clarification on whether organic or conventional agriculture should be the baseline for comparisons. In addition, standards for data collection are needed (Anita *et al.* 2011).

### **Methodological Issues for SECs**

In order to know which data is needed, some decisions need to be made regarding a few basic issues like the scope of the assessment, the spatial and temporal scale of the assessment, or appropriate criteria and indicators. Before discussing the status of the data which might be of relevance for a socio-economic assessment, some general issues, which need to be considered, are presented later in this article. While in an Environmental Risk Assessment (ERA) conducted for the authorisation of GMOs every single event is considered a case and subject to separate assessment, socio-economic effects may rather depend on a specific GM crop species (e.g. soya bean) than on a specific event (e.g. MON89788). One view is that since socio-economic data is crop/trait/application-specific but not necessarily event-specific, that is, there is no need to produce extensive socio-economic data for each particular event. Supplementary event-specific information might only be relevant if important characteristics of the crop/trait/application combination are being affected (Spok 2010). This is important if there is a stacking of traits in an event or a GMO which is being test. However, different countries adopt different norms in regulating them. The differences in regulation with APEC can be illustrated by regulation of stacked events. Within the APEC region Australia, the USA, Canada and New Zealand don't require submission of additional data if the individual traits are already approved and if the combination is not to result in



concerns about safety while Japan treats them as individual or new events and thus separate approvals are needed. While the Philippines and Korea have devised regulation that eschews both the above approaches, Malaysia is yet to develop a policy on this. (Margarita Escaler *et al.* 2012)

On the other hand for LMOs socio-economic effects are very much linked to a certain type of LMO application. Some argue that the excessive cultivation of HR soya bean, accompanied by an increased use of herbicides, has far-reaching socio-economic consequences (for example, decrease of domestic food security, displacement of farming populations (Antoniou *et al.* 2010)). In addition, the outcome of an assessment may differ, depending on the level at which socio-economic effects are studied – either at the microeconomic (e.g. farm level) or at the macroeconomic level (e.g. national level). Therefore, socio-economic impacts and the generation of respective data on a specific crop or trait (e.g. herbicide tolerance) or a combination of these may be important.

The level at which socio-economic effects are studied is of utmost importance for the collection and evaluation of socio-economic data in general, and for the identification of adequate indicators in particular. Today most studies in developing countries are conducted at the farm or the household level, that is, the basis to which all collected data refer to. However, economic analysis can and should also be conducted for whole economic sectors, for example, the seed sector, food trade sector, the food processing industry, commodity trade, or it should be conducted at the level of political units (e.g. communities, regions, countries or federations). In addition, economic models may differ in their underlying assumptions of market situations, e.g. by including or excluding trade. When assessing socio-economic impacts on a certain level, the given environmental, economic and socio-cultural conditions in a country or region need to be considered. Conclusions derived from socio-economic assessments cannot easily be transferred to other countries or regions.<sup>3</sup> Socio-economic impacts are also determined by societal circumstances. It is also important to define the data that need to be generated and the selection of the scientific methods that are to be applied (Anita *et al.* 2011).

Another issue associated with this is the limitations of the availability of data. There are also scientific studies showing the limitations of data availability (e.g. Barbero *et al.* 2008; Smale *et al.* 2009 and Friends of the Earth 2010). Methodology for environmental and health risk assessments is well-developed and implemented in the regulatory process of GMOs,

whereas studies on the socio-economic impact of the cultivation are carried out mainly by academia. However, a recent review revealed that even academic research does not cover all relevant sectors equally (most of the studies focus on the farm level, with fewer studies on the other sectors such as seed, food, feed consumer and social impacts on a broader scale) and that methodology has to be developed further (Lusser *et al.* 2012). Furthermore, studies on wider micro-economic effects (e.g. impacts on non-adopters, household income) are rare in particular for developing countries. Some studies are available on the macro-economic level. Thus it can be argued that comprehensive studies are needed but the methodological issues have to be addressed before undertaking them.

Moreover, there is a need to clarify the formation of normative baselines, key concepts, criteria, impact dimensions, endpoints and methods. The degree of public participation might be flexible depending on the issues at stake. It is also important to consider the characteristics of socio-economic data and the differences compared to data from scientific risk assessment (Spok 2010). A number of methodological issues are associated with the impact assessment of GM crops at farm level, especially in developing countries where researchers collect data in personal interviews with farmers due to the lack of reliable sources and where random sampling may not be feasible. The most commonly applied methodologies have been partial budgets and econometric models of farm production, in which researchers tested hypotheses related to the yield advantages, labour and pesticide savings associated with adoption. Data quality has been a major limitation of early studies, where samples were typically small, field observation periods were brief, and estimates of key parameters were often based on farmers' recall.

Perhaps the most critical concern has been self-selection bias, that is, the fact that farmers adopting the GM technology may also be the most efficient, or those with greater endowments and better access to markets or information. Additionally, the decision to grow a GM crop may be endogenous, and explained by other factors which are unobservable or not integrated into the model (like the pest pressure for instance). Thus these methodological issues can be addressed by using advanced econometric techniques (Lusser *et al.* 2012). But in order to obtain more robust conclusions, multiple methods are needed. Furthermore, there is a lack of rigorous consideration of impacts on labour, health, environment, equity, poverty (Smale *et al.* 2008). Thus for assessments of broader socio-

economic impacts or complex dimensions such as, multifunctionality of agriculture quantitative methods alone may not be sufficient and need to be combined with qualitative methods (Spok 2010).

In a recent article Glen Stone has pointed out that both supporters and opponents of Bt Cotton in India claim that their arguments are based on 'facts' and these 'facts' are repeatedly used to buttress their claims. He points the issues in constructing and interpreting these facts and argues that biases like self-selection have to be considered in understanding the claims based on these 'facts' and interpretation of the studies based on empirical field work. In the case of Bt Cotton an important and contested claim is that Bt Cotton has contributed significantly to the increase in the cotton output in India in 2002-2012. In 2002 Bt cotton was approved for commercial cultivation. (Stone 2012)

### **Indicators for Measuring SECs**

A methodological framework should be built up to define socio-economic indicators that have to be monitored and to establish appropriate rules for data collection (Lusser *et al.* 2012). Though it is important to define criteria and indicators for the assessment of socio-economic impacts, it is also necessary to define a common starting point and provide a framework for the discussion process of this broad and complex issue (Anita 2011). For example, COGEM has formulated nine themes and criteria which can serve as building blocks in an assessment of the contribution of GM crops towards more sustainable agriculture. Many socio-economic aspects which need to be accounted for in LMO cultivation are summarised in it. The closely related building blocks are as follows: benefit to society, economics and prosperity, health and welfare, local and general food supply, cultural heritage, freedom of choice, safety, biodiversity and environmental quality. For the operationalisation of these criteria, it is desirable that the indicators used to measure these criteria are objectively measurable and can be estimated in advance (COGEM Report 2009).

In fact, there are differences which can be found in practice for instance while comparing National Sustainability Plans of the countries (NSDS) while adopting these criteria. These differences translate into indicators which vary widely across countries. Some NSDS specify relatively few (mostly environmental) indicators. Others have adopted large indicator systems (OECD 2006). A survey of NSDS of the EU Member States also revealed differences in the dimensions considered. Some Member States consider additional dimensions also; for instance, Slovakia, Poland, the

Czech Republic, Estonia, Slovenia, and France have added an explicitly cultural dimension to the strategy emphasising local traditions, value systems, arts and the preservation of historical and cultural heritage as an integral part of sustainable development (Spok 2010). But many of these are difficult to measure and the concept of sustainable development is like an umbrella word under which one can place any factor or socio-cultural-economic dimension. Ivan Illich wrote about amoeba words whose meanings keep changing according to the users and contexts. The linkage between sustainable development, LMOs and socio-economic aspects is turning out to be an exercise in adding more to a wish list than an exercise in a realistic assessment. In our view, this approach by European countries is not suitable for developing countries or LDCs where food security and farm productivity are major issues. By adding more elements or criteria to socio-economic aspects no useful purpose will be served.

But the alternative to the European approach is not neglecting SECs or using them as a cosmetic piece in the regulatory and decision making process. In our view, there is a strong case for an appropriate and integrated framework in SECs in decision making. The framework we propose will consist of two different and distinct levels of decision making on LMOs. The first level will be regulatory decision making based on scientific and technical aspects. In this the safety, efficacy aspects, including health and environmental impacts, will be considered as key parameters to take a decision. With respect to environmental impacts while impact on biodiversity will be considered that will be solely on natural biodiversity and will eschew linking culture and biodiversity or values and biodiversity in regulation and decision making. This level of decision making will consider safety, efficacy and effectiveness as three criteria to assess, *prima facie*, the technology *per se* and its utility.

### **Safety, Efficacy and Effectiveness – The Three Issues in Assessment of Technology**

Safety includes food safety, environmental safety and is assessed through risk assessment and by following globally accepted guidelines to assess safety (for example, WHO standards, CODEX guidelines) and accepted practices to evaluate the quality and sufficiency of experiments done in labs and field experiments. The accepted practices are available and are in public domain. Unless safety assessment is made no permission is granted to commercialise.

Efficacy has direct socio-economic implications as it is tested by comparing the agronomic performance with the projected/estimated performance. Efficacy can be quantified and verified and it can be tested over a period of time also. For example, if it is projected that Bt toxin in BT plants will kill 70 per cent of the target insects this is measurable and verifiable in field trials and similar claims can be verified. There are benefits that may not be claimed or projected but may arise on account of efficacy. For example, while the primary efficacy can be tested in terms of percentage of target pests killed, increase in yields and reduction in use of pesticides are not the primary measures of the efficacy of (Bt) technology. The direct socio-economic implications of efficacy are to be taken into account. In other words, the more the efficacy is, more may be the socio-economic implications in terms of different parameters.

Safety and efficacy are determined by technology and hence are technology dependent. Evaluating safety and efficacy is an assessment of technology per se and not technology as applied. Hence, any assessment of both these cannot be translated into direct socio-economic implications for decision making. These assessments may indicate the socio-economic implications.

**Effectiveness:** The effectiveness of a technology is tested under different conditions and in different contexts. Effectiveness is often influenced by factors that are outside technology and hence efficacy and effectiveness have to be understood as two categories. For example, Efficacy studies may indicate results which may not be repeated in commercial cultivation. For example, if a Bt variety recommended for cultivation in irrigated land is used in dry land agriculture then the outcomes are likely to be different from what studies on efficacy pointed out. Environmental factors, cost factors and other factors like handling/management of technology affect the effectiveness and as a result the variance in effectiveness is the result of many factors that have nothing to do with technology per se. But for assessing socio-economic impacts studies on effectiveness are necessary as they indicate the outcome of technology as applied in different conditions. But here too it is desirable to do *ex-ante* and *post-ante* studies and assess the performance in real world.

**Regulation:** For a regulator assessing the technology per se, assessing the two, technology dependent factors are critical because *prima facie*, whether the technology can be approved or not is the issue. Unless the technology meets the norms, the regulator can refuse permission to commercialise it.

But even after one regulator approves it, there can be other norms that have to be met for commercialisation or application on a wider scale.

For example, a Seed Regulator may stipulate that new seed varieties that show less than 10 per cent yield increase in coordinated field trials in different climatic zones will not be approved for cultivation as they do not meet the effectiveness criteria although they might have met the efficacy and safety criteria.

### **Incorporating Socio-economic Aspects in Decision Making**

The second level decision making will give importance to socio-economic aspects but socio-economic aspects will in general be limited to a maximum of six issues/parameters that are appropriate and relevant with respect to the LMO/GMO in question. From these six issues the most important three issues will be identified based on their relevance. Comprehensive studies on socio-economic aspects of them will be done and suitable methodologies will be developed. For example, economic impacts in terms of productivity, income for farmers, reduction in inputs and their costs are important in determining whether the LMO/GMO is a better one in terms of economic indicators. The social dimension is important but deciding on the social aspects or factors that need to be understood and studied cannot be decided a priori for all LMOs/GMOs. But how to choose the most appropriate social indicators or aspects is an important question. One way to approach this is to use methods like surveys, dialogues with stakeholders including those communities/classes that will be impacted upon by the proposed use of LMO/GMO to identify what issues/factors matter to them most in this issue. For example, in case of indigenous communities their perception that this LMO/GMO may violate their cultural norms may be important, perhaps more important economic impacts where as for other communities this may not be an issue. In such cases the decision making process should be sensitive to these perceptions and try to address them.

While most of these socio-economic assessments/studies will be done in Pre-Production stage, there are socio-economic considerations that are important in other stages also as briefly described in Table 1.

In the integrated framework we suggest that assessment of technology and assessment of socio-economic aspects should be done at distinct levels. The socio-economic aspects should be integrated in the framework not as an after thought or for the purpose of data collection but for the purpose of assessing the impacts of LMO/GMO including socio-economic aspects.

**Table 1 Proposed Socio-economic Considerations for LMOs  
at various Stages**

<b>Pre-Production</b>	<b>Production</b>	<b>Marketing</b>	<b>Post Production Monitoring</b>
<ul style="list-style-type: none"> <li>• Testing of efficacy and environmental and health safety.</li> <li>• Assessments are based on globally accepted methodologies, protocols and standards in testing and data analysis.</li> <li>• Safety assessments need science based risk assessment based on quantifiable, verifiable and experimental evidence.</li> </ul>	<ul style="list-style-type: none"> <li>• Testing of effectiveness of the technology.</li> <li>• Many factors influence effectiveness including technology independent factors.</li> <li>• Results of effectiveness tests may vary from results of efficacy tests.</li> <li>• Tests of effectiveness can be directly relevant for socio-economic impacts.</li> </ul>	<ul style="list-style-type: none"> <li>• Traceability and labeling of LMOs.</li> <li>• Products can be withdrawn if unforeseen adverse effects on human/ animal health or on environment are revealed.</li> <li>• Gives correct information to the consumers.</li> </ul>	<ul style="list-style-type: none"> <li>• Tests the long terms impacts.</li> <li>• Investigates the occurrence of any potential adverse effects of a LMO that were identified during the pre-production phase and assess their significance.</li> <li>• Identify the occurrence and impact of unanticipated adverse effects of LMOs that were not predicted in pre-production assessments.</li> <li>• Post production data is compared against the baseline data of the environment in which the LMO has been introduced.</li> </ul>

*Source:* Chaturvedi, Sachin, Srinivas, Krishna Ravi, Joseph, Reji K and Singh, Pallavi. 2012.

The assessment of socio-economic aspects is necessary but not sufficient to take informed decisions. In some cases even when the economic impact is beneficial, the environmental impact on biodiversity may be a reason for not granting approval. In some cases it is necessary to ensure that there is no 'contamination' from GM crops to crops which enable a country to earn huge foreign exchange because of quality of produce and the distinct features of the produce (e.g. Basmati). In this case the trade dimension is too important to be ignored. The differentiation among Socio-economic Considerations as indicated in the Table 1 in different phases is necessary so that depending upon the effects, policy making can be done. Thus, in this

approach socio-economic considerations are taken into account depending upon their relevance for decision-making.

## Conclusion

Incorporating socio-economic aspects into decision-making is a challenge as there are many methodological issues to be resolved and there is no consensus on what constitutes socio-economic aspects. The European approach is comprehensive but not useful for developing countries as that approach does not method a methodology that is relevant in the developing nations' contexts. Different countries have addressed this question in different ways. In this article, we have given the outline of one approach which in our view is more appropriate for developing nations and Least Developed Countries as this differentiates regulation from assessment of socio-economic aspects and at the same time ensures that socio-economic considerations are given due consideration in different stages of commercialisation.

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## Endnotes

- <sup>1</sup> See Meyer, 2011
- <sup>2</sup> See Agenda 21: Programme of Action for Sustainable Development, U.N. GAOR, 46th session, Agenda Item 21, UN Doc A/Conf. 151/26 (1992) at Chapter 16, paragraph 38.
- <sup>3</sup> Socio-economic studies lead to different results and conclusions, depending on the context chosen and the conditions prevailing at the time of collecting the data (Kaphengst *et al.* 2011).



## Book Review

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### ***Europe's Green Revolution and Others Since: The Rise and Fall of Peasant-Friendly Plant Breeding***

Author : Jonathan Harwood  
Publisher : Routledge (2012)  
ISBN : 978-0-415-59868-2 (hardback)  
Pages : 270  
Price : U.S. \$ 140.00



In this incisive book, the historian of science and technology Jonathan Harwood meets with noteworthy success in his forthright attempt at a dialogue between the history of European agriculture and development studies. This book should be required reading for every student of the Green Revolution and contemporary debates regarding agricultural development.

Harwood's latest publication contains an introduction followed by eight chapters. As the author usefully points out in the introductory chapter, his work is aimed at a variety of audiences, with some of the chapters relevant to agricultural historians (Chapters 1 through 5, which trace the rise and fall of peasant-friendly breeding in Europe between 1880 and 1945), and others (Chapters 6, 7 and 8, which record the extraordinary degree to which post-1945 Green Revolutionaries appear to have dismissed the success or failure of earlier development programmes) appealing more to those academics and practitioners concerned with development of the global South. Those interested in questions of science and public policy are directed to focus upon Chapters 4 and 8 that have to do with the mantra that public-sector institutions should fix their attention on fundamental research, leaving applied work to the 'more efficient' private sector. Since it is difficult to do justice to the entire book in a short review, I will concentrate on those arguments and evidence presented by the author that would be of the greatest interest to the readers of this journal on agri-biotechnology and development.

In the preface, the author states that he has three objectives in mind: first, to contribute to the emerging literature on the history of plant breeding, which aims to connect breeding in absorbing ways to a range of general issues. Harwood remarks that the emerging body of work is

significant because it gives us a perspective to better understand and evaluate current controversies surrounding the genetic engineering of organisms and the patenting of life forms. To this end, in Chapter 4, he presents a history of the disputes between the state-funded public sector plant breeding stations and private sector companies engaged in that same work in south Germany during the phase 1902-1933. He gives evidence that public sector support for small firms is important for innovation across the sector as a whole, and he argues that large companies are interested in dominating the seed market by destroying competitors (small firms or the public sector institutions) in the name of 'competition' and the 'free market.'

His second objective is to present a magnified and revised history of the Green Revolution. Conventionally, the Green Revolution is supposed to begin around 1945 and end in the 1970s. However, Harwood locates the beginnings of the Green Revolution in late nineteenth century Europe. He gives more attention to the later phases of the history of the Green Revolution, that is, from the 1970s to the present. As Harwood mentions, the gain from stretching out the Green Revolution to cover the period 1880-present is that the patterned nature of its history becomes more evident. The author draws upon secondary sources to argue that the Green Revolution has gone through alternating phases in which its principal interest has shifted between boosting production and securing social equity. Thus, the chief concern of Green Revolutionaries during the first phase (1945-1970) was to boost production while that of the proponents of the second phase (1970s and 1980s) was to focus on social equity. Productivist concerns have become prominent during the third phase (1990 onwards), which is also the age of the 'Gene Revolution' or agri-biotechnology or the 'Second Green Revolution.'

The author's third objective is to show how the history of Green Revolution might be of practical use in informing development policy. The idea is that institutions, including the development industry, have something to profit from reflecting upon their experience. Harwood claims that his analysis shows a surprising lack of interest by the development industry in its own past. He comments that the need to 'look back' before taking decisions regarding the future has become pressing since the 1980s through the ascendancy of neo-liberal political thought in many countries. Remarking on the task of the historian of agricultural development, he writes on page xv: "That markets should routinely be given preference to state action, however—not least in development policy—seems to me to

be grounded far more in ideology than in the analysis of past action and its consequences. There is a great deal at stake here, and it is important that those of us who know something about the past should speak up."

Apprehensive about being pigeon-holed as a technology-pessimist, Harwood makes it clear in his prefatory remarks that he is not a Luddite (defined by him as "critics of quasi-romantic inclination who attack the technology central to industrial agriculture for poisoning our food, contaminating the environment, and fatally undermining the family farm. For them, the solution is seen to lie, not in improved technology, but in indigenous knowledge and 'traditional' cultivation practices."). Neither is he a 'high modernist' (*cf.* Scott 1998), those who advocate the 'modern' agricultural science underpinning the Green Revolution as the only effective way to prevent the occurrence of hunger and poverty in developing countries. Terming both Luddite and 'high modernist' visions as exclusive, Harwood argues against such exclusivism, and says that the "most promising solutions to rural hunger and poverty [whether in Europe around 1900 or in the contemporary global South]...are instead those that are synthetic; they combine the methods of science and technology with the best that indigenous knowledge and practice have to offer (page xvi)." However, Harwood does not provide any examples or case-studies of appropriate technology in the global South that have successfully met the challenges of both low yields and social inequity. If such examples do not exist in history, then the task of creating synergy between 'high modernist' (whether they belong to the private sector or the public sector) and 'Luddite' visions in the age of biotechnology becomes all the more difficult. Another problem is that Harwood does not make it clear how his use of the term 'appropriate technology' differs from the common usage of that term (for example, by Ernst Schumacher in his 1973 book *Small is Beautiful*) in the literature on development studies. Does the term 'appropriate technology' envisage any role for large private-sector firms in the seed markets, or does it see a future only for public sector breeding stations which co-exist with many small private-sector firms? Does the term 'appropriate technology' resonate with the prohibitively costly transgenic technology? Is biotechnology-based agriculture amenable to local (by which I mean community-based) control? These are just a few questions that emerge upon reading about Harwood's championing of 'appropriate technology' as a way to effectively deal with both Luddism and high modernism.

I will briefly address the central goals of each chapter. The first five chapters of the book have to do with the appearance of the south German plant-breeding stations as well as their work, impact and decline. Chapter 1 deals with the political and economic context within which nineteenth century German agricultural authorities decided to establish peasant-oriented institutions for extension and research. In Chapter 2, the center shifts to south Germany during the 1890s where a conjuncture of movements and concerns prompted agricultural ministers to see state-funded plant breeding as both economically and politically desirable. In the third chapter, the author narrates the early history of the south German stations up to 1914, noting their organisation, growth and activity in varietal testing, breeding and extension work. Chapter 4 deals with the interwar period, by which time the state-funded plant breeding stations had begun to make a definite economic impact but also became immersed in disputes. The chief focus of Chapter 5 is the period of National Socialism when, despite the regime's oft-announced support for peasant agriculture, the stations came under considerable pressure to abandon their peasant-friendly mission in order not to compete with private-sector breeding.

The last three chapters trace the history of the Green Revolution from the 1940s into the contemporary phase. In Chapter 6, after introducing the Green Revolution and its critics, Harwood examines the efforts by development experts from the 1970s to establish why the revolution had largely failed to benefit smallholders. Their diagnoses are then 'tested' against a particular case: the early history of the Green Revolution in Mexico. In the next chapter, he asks to what extent this period of criticism and reflection gave rise to peasant-friendly reforms of the Green Revolution, beginning with new approaches from the 1970s (agroecology, farming systems research, participatory plant breeding). It concludes with an assessment of the status of peasant-oriented approaches today and an examination of the recent claims that biotechnology offers the most promising foundation for a 'second Green revolution.' In Chapter 8, Harwood places the history of the Green Revolution in a wider political-economic context, summarised the argument that state-funded agricultural research offers a viable development strategy for peasant farming, but conceded that such a strategy is unlikely to make much headway so long as the development industry remains structured as it is.

Harwood comments that though some claims for biotechnology's peasant-friendly potential are entirely plausible (and gives examples of such innovations), the key question is: what is the likelihood that this potential

payoff will be realised? The author explains how the public sector has been deliberately rundown in all countries since the 1980s and there are no signs that this situation is changing. The private sector is now dominant in biotechnology. Regarding public-private partnerships to solve the funding problem, Harwood warns that the terms of such collaboration will have to be negotiated very carefully. For example, NGOs have already expressed concern that some of the CGIAR centers' existing partnerships threaten to divert the center's work away from the needs of small farmers. So, what are the prospects for biotechnology-based breeding helping resource-poor farmers in future? Harwood argues that the concentration of biotechnology in the private sector, the weakness of public-sector agricultural research, and the very few public-private partnerships so far all suggest that these prospects are poor. Indeed, some argue that the diffusion of biotechnology in the developing world is likely to widen the gap between commercial and subsistence farmers, and the evidence from Latin America seems to bear this out. Faced with such evidence, many advocates of biotechnology insist that the technology will be capable of serving smallholders once a series of 'obstacles' have been removed. It is essential, they argue, that (a) the private sector be encouraged to invest in this area (e.g. through protection of intellectual property rights, reasonable biosafety regulations, and state-funded incentives which encourage pro-poor research) and (b) governments in the South fund public-sector biotechnology research and provide input subsidies to small farmers. This optimistic view, however, turns a blind eye to the serious limitations of both private and public sectors. By arguing that governments in the global South merely need to get their policies on biotechnology right, advocates have simply ignored the fundamental political fact that over the last thirty years or so, the public sector has been deliberately weakened in all countries except for China. Harwood provides some excellent evidence of what Chinese public sector has done for peasant farmers in that country, but it would have been more useful if he had devoted a chapter to show how the post-1949 Chinese state's attempts to meet the needs of peasant farmers converges with or diverges from the past peasant-friendly Green Revolutions in Europe and Japan.

Harwood poses the question: if the evidence is so unconvincing that the developed world's biotechnology will alleviate rural poverty, why do the proponents of biotechnology never seem to tire of advancing this claim? The author gives reasons as to why three social groups (scientists, biotechnology industry, and major donor agencies) have jumped on the biotechnology bandwagon. Scientists are lured by the promise of

an easy technological fix for all kinds of socio-economic problems. The biotechnology industry focused on the poverty-alleviation claim during the 1980s in order to make a business case to investors, and since 2000 in its zeal to combat the European people's intransigence on transgenic crops. Regarding the donor agencies, Harwood opines that one might have hoped that these organisations' familiarity with the complexities of development might have vaccinated them against unduly simple solutions. If 'miracle seeds' could not deliver the poverty alleviation that was promised in the first generation of the Green Revolution, why should one expect a 'miracle technology' to do so in the third generation? The answer here, Harwood thinks, requires us to reflect upon the very nature of the development industry, a task he defers to the last chapter.

In the last chapter, the author looks upon the material he has presented in the last eight chapters from three different perspectives. He draws conclusions which are respectively analytical, hopeful and bleak. The first of these is an attempt to place the material the author has surveyed within a wider theoretical framework. The second is a normative conclusion in which he outlines what he believes the implications of his historical analysis are for development policy. The third perspective is a rather pessimistic series of reflections upon the nature of the development industry today whose implications is that, given the way in which it currently operates, 'the lessons of history' are unlikely to make much impact upon development strategy.

Harwood expresses the view that International Agricultural Research Centres (IARCs) and National Agricultural Research System (NARS) can be potentially of crucial importance for smallholders provided they are adequately funded by different entities. He states that if rich countries were to divert just two per cent of their agricultural research budgets to the developing world's NARS, the latter's budgets would more than double. Undoubtedly, there is plenty of money available which could be used to strengthen the global South's public-sector R&D. He comments that if rich countries choose not to spend it in this way, it is a political decision. Later, in this chapter, he agrees with Gilbert Rist (2008)'s stringent critique of development as an "ideological commitment and a vehicle for achieving a range of often political aims, not an empirically based learning process that seeks poverty alleviation." If we have indeed reached an impasse when it comes to agricultural development, then why did the author bother to argue the case that peasant-friendly development can be fostered by state

research institutions? Harwood gives some evidence to make his point that the development industry is not monolithic, and this very existence of pluralism makes him hope as a historian that some development agencies, theorists and practitioners will reflect upon the past while trying to devise more effective strategies for the future. One hopes that this important contribution by Harwood to the literature on agricultural development combined with his earnest plea for the revitalisation of state-funded research institutions will reach the ears of biotechnologists and policymakers in both rich and poor countries.

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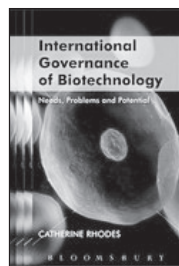


## Book Review

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### ***International Governance of Biotechnology: Needs, Problems and Potential***

Author : Catherine Rhodes  
Publisher : Bloomsbury Academic, London. 2010  
ISBN : 9781849660655  
Pages : 210+xiv  
Price : £50.00 (hard cover)  
DOI : <http://dx.doi.org/10.5040/97818496618121>\*



Regulation of technology at a global level is a challenging task, particularly for technologies like biotechnology that have wider applications in many fields with rapid advances in the technology. If at all anything easy answers elude the question of regulating nanotechnology and synthetic biology, whether it is at national level or regional level or global level<sup>1</sup>. On the other hand, regulatory divergences are more a norm across nations than an exception in many fields including regulating drug safety.<sup>2</sup> Thus, while there may be a need for global regulation of some technologies given their impact and wider use, it has not been an easy task to evolve a global regime or a Treaty or Convention for this purpose. Part of the problem lies in differences in approaches to risk assessment and also the variance in public policy that sets the limits for application of a technology.<sup>3</sup>

In the book under review Catherine Rhodes embarks on a challenging task – arguing for international regulation of biotechnology by examining the current regulatory frameworks relevant to biotechnology at the global level. Although the title mentions Governance the book calls for international regulation which is synonymous with Governance. Topics like this can be analysed from different disciplinary perspectives and the author has chosen International Law as the discipline to ground her analysis and to make a case for international regulation.

Chapters 2, 3, and 4 discuss the biotechnology revolution, its impacts and potentials, and the need for regulation. In the next two chapters,

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\* This book can be read online at <http://www.bloomsburyacademic.com> for free after registration

the author examines the model for coherent international regulation and identifies thirty seven international regulations that are relevant in regulation of biotechnology. In the next five chapters, the author provides an extensive analysis of the regulations and compares them with the model regulation that she considers as desirable and assesses the regulations in terms of sixteen characteristics. Finally, based on these chapters she argues for regulation at international level for effective governance of biotechnology revolution so that while its benefits are maximised, the negative impacts are eliminated or minimised. In this regard, she examines the coherence or its lack among these regulations and suggests how more and better coherence can be ensured. Thus, the conclusion is a call for international regulation of biotechnology which will be based on some core principles.

The important chapters from the point of view of the reviewer are from five to eleven in which she analyses the current regulations and points out the problems with them so as to build an argument for international regulation. However, I find it problematic that her set of regulations includes agreements like TRIPS or guidelines for biosafety and international agreements whose central concern or objective is not regulation of biotechnology. Thus, if one applies a different criteria or definition of regulation, then the number of regulations will be reduced considerably as only agreements, treaties and Declarations, whose core objectives are related to or include biotechnology regulation, need to be considered. Moreover in case of declarations she has cited they are more concerned with what is permissible and what are desirable and not desirable than regulating biotechnology per se. For example, the Declaration on Cloning indicates what is permissible and what is not but regulation of a technology is more than that, although the boundaries of application of technology are set by such declarations and often by national level policies that are consistent with such declarations. Thus, if one goes by a stricter definition of regulation then not only the number of regulations is reduced but also a portion of the subsequent analysis by the author becomes redundant. This I think is a major issue with the book because not all may agree with her categorisation of relevant regulations. Some of the regulatory hurdles at the international level stem from lack of coherence among regulations and also from universally accepted norms of risk governance. The interface between trade regulation and environmental regulation is another issue that is very relevant to the questions raised by the author. But these do

not get the attention they deserve in this book as the author deals with as many as thirty seven regulations and her analysis summarised in tables is revealing and important.

The author takes the Geneva Conventions and Protocols as model as they provide coherent set of international regulations and also points out that the same is true of Dangerous Goods Regulation and UN Drugs Convention. But these are not dealing with a fast advancing technology and hence while they may be models of international regulation, they cannot be considered as models for international technology regulation. Hence the question that should have been pursued is what is an ideal or preferable model for technology regulation at the international level, that also has key features of accepted models of international regulation from an international law perspective. The models she has chosen are not totally irrelevant as she is analysing them in terms of key principles and how they are coherent with each other. Thus the point that coherence among regulations is important and in that aspect the examples are very apt.

Based on the model and her detailed analysis of each of these regulations in terms of structure, institutional mechanism she critically examines their shortcomings and how these regulations lack coherence with each other and points out the overlap among them. This is the core of her argument and this is well developed, and the criteria she has used are very useful in unraveling the coherence or its lack and the scope of each of the regulations. According to the author, "The biotechnology regulations fail to match the four characteristics of the coherent regulatory model covered in this chapter. There is some self-referencing among regulations within and between issue areas, but not for the set as a whole and not always with relevance to control of biotechnology" (pp.144). Similarly, she identifies 15 institutions that are relevant for biotechnology regulation.

Using 16 characteristics and 15 functions as criteria she evaluates the international regulations applicable to biotechnology and points out that they lack coherence and provides examples for this. But some of the examples are not convincing, partially because, as pointed out earlier, some of the regulations are not relevant to regulating biotechnology at the global level (e.g. TRIPS Agreement, Bonn Guidelines). Hence, in my view, her argument on existence of different dispute settlement mechanisms (pp.166-167) is not valid. While in some instances, there are issues like which Treaty or Agreement is applicable, this aspect has not got the attention it deserves by the author. For example, the question of using Socio-Economic Aspects

under Article 26 of Cartagena Protocol to block import of Living Modified Organisms (LMOs) is cited by the author in the context of whether this is applicable or whether WTO rules apply. But the analysis is too brief and it does not even scratch the surface. A deeper analysis would have revealed that while this is an important question, part of the answer lies in Article 26 itself which recognises obligations under other international treaties. Thus while there is scope for dispute under WTO in such a case, the issue would be different and that would be whether such an action, that is blocking import of LMOs, is consistent with WTO rules or not. In fact, the author could have used this example and cases before WTO, to point out the major problems in current regulation of biotechnology. Having exhaustively analysed these regulations she builds up a case of international regulation of biotechnology and makes suggestions that would enhance coherence among international regulations.

The author has tried to address an important problem and has come up with some suggestions. But on account of the problematic nature of the set of regulations in terms of their applicability as regulations of biotechnology, subsequent analysis suffers from many flaws, some of which have been pointed out in the previous paragraphs. The author could have explored linkages and interfaces in trade and environment disputes and could have used the extensive literature on WTO cases to buttress her case for coherent international regulation of biotechnology.

However, whether such a global regulation is feasible, or for that matter desirable, is a different issue. One way to address this issue is to examine whether in some applications of biotechnology, international regulation is necessary to meet some objectives and if so what are those applications and how to develop and deploy global regulation for such applications. Given the broad and expanding nature of biotechnological applications and uses, it is better to categorise in terms of applications in a field (e.g. health biotechnology) and examine the case for international regulation, and ensure that the interface and linkage between set of regulations in this area/application and other important agreements like WTO are well understood and scope for coherence is increased, than to argue for a global regulation for whole of biotechnology. It is true that although there are issues with current regulation of biotechnology under different agreements, conventions and treaties, the situation is not so alarming to call for a global regulation as envisaged by the author.

As a book that addresses an important issue in regulating biotechnology, this will be of interest to anyone interested in global regulation of technology and international law and technology. It raises many important questions, most of which elude easy answers.

--K. Ravi Srinivas

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## Endnotes

- <sup>1</sup> "Looking Back to the Future of Regulating New Technologies: The Cases of Nanotechnologies and Synthetic Biology" by Elen Stokes and Diana M. Bowman. *European Journal of Risk Regulation* No 2, 2012 pp. 234-241; Falkner, Robert and Nico Jaspers .2012. "Regulating Nanotechnologies: Risk, Uncertainty and the Global Governance Gap". *Global Environmental Politics*, Vol. 12, No. 1, pp. 30-55.
- <sup>2</sup> Daemmmrich, Arthur A. *Pharmacopolitics: Drug Regulation in the United States and Germany*. University of North Carolina Press, 2004; and "Thalidomide and Its Sequelae" by Michael Emanuel, Michael Rawlins, Gordon Duff, and Alasdair Breckenridge. *The Lancet* Vol 380 September 1, 2012, pp. 781-783.
- <sup>3</sup> *Designs on Nature: Science and Democracy in Europe and the United States* by Sheila Jasanof. Princeton University Press, 2007.



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More than one reference of the same date for one author should be cited as 'Shand 1999a, 1999b'.

The following examples illustrate the detailed style of referencing:

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**(b) Edited volumes:**

Shand, Ric (ed.). 1999. *Economic Liberalisation in South Asia*. Delhi: Macmillan.

**(c) Articles from edited volumes:**

Lakshman, W. D. 1989. "Lineages of Dependent Development: From State Control to the Open Economy in Sri Lanka" in Ponna Wignaraja and Akmal Hussain (eds) *The Challenge in South Asia: Development, Democracy and Regional Cooperation*, pp. 105-63. New Delhi: Sage.

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Sandee, H. 1995. "Innovations in Production". Unpublished Ph.D thesis. Amsterdam: Free University.

**(f) Online Reference:**

World Health Organisation. 2000. "Development of National Policy on Traditional Medicine". Retrieved on March 31, 2011 from <http://www.wpro.who.int/sites/trm/documents/Development+of+National+Policy+on+Traditional+Medicine.htm>

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